FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

INSTRUCTIONS FOR COMPLETING FORM 3500A

(Specific to Medical Device Reporting)

With

CODING MANUAL FOR FORM 3500A

December 14, 1995

FOR FURTHER INFORMATION OR QUESTIONS CONTACT
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FOREWORD

The Food and Drug Administration (FDA), has established the final reporting requirements for Device User Facilities and Manufacturers under the revised Medical Device Reporting Regulation, 21 CFR, Part 803. The final reporting requirements for Distributors is contained in 21 CFR Part 804. These regulations enact a uniform system for the submission of reports of deaths, serious injuries and certain malfunctions associated with the use of medical devices. These reports must be submitted to the FDA and/or the manufacturer on FDA Form 3500A (MedWatch form).

The FDA has developed this guidance document to assist User Facilities, Distributors and Manufacturers in complying with the requirements established in Parts 803 and 804 when completing applicable sections of Form 3500A. The Coding Manual for Form 3500A is also included, and it contains instructions for proper identification and utilization of the adverse event and manufacturer evaluation codes which must be provided when filling out certain sections of Form 3500A. Various references, including telephone and facsimile numbers, addresses for obtaining copies of this document and Form 3500A and other sources of information are also included in this document.

These final instructions for completing FDA Form 3500A with the coding manual replaces all versions previously in

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INSTRUCTIONS FOR COMPLETING FDA FORM 3500A

These instructions and FDA Form 3500A should be used by user facilities, distributors, and manufacturers for **MANDATORY** reporting of adverse events and product problems associated with the use of medical devices, as designated in the applicable statues and FDA regulations. Form 3500A should also be used by User Facilities to report, voluntarily, malfunctions and other product problems which did not cause or contribute to a death or serious injury.

- All entries should be typed.

- Complete all sections that apply. When information is not readily available, select one of the following:

  - **NA** for not applicable
  - **NI** for no information at this time (but may be available at a later date)
  - **UNK** for unknown

- Dates should be entered as month/day/4-digit calendar year (e.g. June 3, 1995 = 06/03/1995). If exact dates are unknown, or only a portion of the date is known (e.g. month/year), provide the best estimate.

- A computer-generated facsimile of the form may be submitted in lieu of the preprinted form if the submitter has received written preapproval from the MEDWATCH office. (see address on page 14). It is acceptable to reproduce each side of the pre-printed form on two separate, front-only pages.

- At the top-right corner, enter the manufacturer report number, user facility number or distributor number in the correspondingly labeled box. Complete both report numbers, if applicable, in order to cross-reference this report with a report from another source on the same event. For follow-up (i.e. supplemental) reports, the number should be identical to the number assigned to the original report.

- The **distributor report number** consists of three components: The FDA-assigned registration or identification number for the distributor of the device, the four-digit calendar year in which the report is submitted, and a consecutive five-digit sequence number for each report filed during the year by the distributor (e.g 1234567-1995-00001, 1234567-1995-00002). If a distributor does not have an assigned identification number, it should use all zeros in the appropriate space on the initial report, and continue to use zeros on subsequent reports until the FDA-assigned number is received. The distributor report number is also entered in block F2.

  The **manufacturer report number** consists of three components: The manufacturer's FDA registration number for the manufacturing site of the reported device, the four-digit calendar year in which the report is submitted, and a consecutive five-digit sequence number for each report filed during the year by the manufacturer (e.g. 1234567-1995-00001, 1234567-1995-00002). If the manufacturing site does not have a registration number, then FDA will assign a temporary one, to be used until the site is officially registered. The manufacturer report number is also entered in block G9.

MANUFACTURER AND DISTRIBUTOR REPORT NUMBERS (continued)

In cases where a reporting site is registered as both a manufacturer and a distributor, and the registration and/or FDA-assigned identification numbers are identical for both, than the five-digit sequence number for reports submitted during the year by either one, may not be duplicated. For example, in the role of manufacturer, the report number would consist of the registration number, a 4-digit calendar year, and a five-digit sequence number, (e.g. 1234567-1995-00001, 1234567-1995-00002, etc.). In the role of distributor, the registration number and year would remain the same, but the five-digit sequence number must be different, (e.g. 1234567-1995-00003, 1234567-1995-00004, etc.).

- The **user facility report number** consists of three components: The facility's 10-digit Health Care Financing Administration (HCFA) number, the 4-digit calendar year in which the report is submitted, and a consecutive 4-digit sequence number for each report filed during the year by the facility (e.g. 1234567890-1995-0001, 1234567890-1995-0002). If the HCFA number has fewer than 10 digits, fill in any remaining digits with zeros. If a facility does not have a HCFA number, the first report and any subsequent reports, should be submitted with all zeros in the HCFA space, and FDA will assign a number to be used in future reports (e.g. 0000000000-1995-0001). If a facility has more then one HCFA number, the facility must select one of those numbers, and use the same number for subsequent submissions. The user facility report number is also entered in block F2.

  If a user facility has multiple sites, the primary site can report centrally and use one reporting number for all sites if the primary site provides the name, address and HCFA number for each respective site.

- If the fields do not provide adequate space for narrative entries, attach an additional page(s) and indicate the appropriate section and block number next to the narrative continuation.

- At the top of both the front and back page, enter the page number and the total number of pages submitted (include attachments in the total). All attached pages should be identified as page _of_ and should display the user facility, distributor, or manufacturer report number in the upper right corner as applicable.

SECTION A: PATIENT INFORMATION

If more than one patient was involved in the same event, complete all applicable sections of the form for the first patient and all of Section A and blocks B2, B5, B6, B7, D10, and F10 for each additional patient. For each additional block F10 enter the corresponding patient identifier in block F3.

A1: **Patient Identifier** - Provide the patient's initials or some other type of identifier that will allow both the submitter and the initial reporter (if different) to identify the report if contacted for follow-up. **DO NOT** use the patient's name or social security number. (The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law).

SECTION A: PATIENT INFORMATION (continued)

A2: **Age** - Enter the patient's birthdate, if known, or the patient's age at the time of the event onset. For age indicate time units used, e.g. years, months, days. Provide the best estimate if exact age is unknown.

- if the patient is **3 years or older**, use **years** (e.g., 3 years).
- if the patient is **less than 3 years old**, use **months** (e.g. 24 months).
- if the patient is **less than 1 month old**, use **days** (e.g., 5 days).

If the adverse event is a congenital anomaly, use the age or birthdate of the child or the date pregnancy is terminated. If information is available as to the time during pregnancy when exposure occurred, provide that information in narrative block B5.

A3: **Sex** - Enter the patient's gender. If the adverse event is a congenital anomaly, report the sex of the child.

A4: **Weight** - Indicate whether the weight is in pounds (lbs.) or kilograms (kgs). Make a best estimate if exact weight is unknown. If the adverse event is a congenital anomaly, use the weight of the child.

SECTION B - ADVERSE EVENT OR PRODUCT PROBLEM

B1: **Adverse event and/or product problem** - Choose box 1 to report an adverse event and/or box 2 to report a product problem. An adverse event is selected when reporting a death or serious injury. Product problem is selected when reporting malfunctions that could lead to a death or serious injury if it were to recur. Both boxes should be checked if a malfunction or product problem caused a death, or serious injury.

B2: **Outcomes attributed to adverse event** - Check all that apply to the reported event.

Death - Check if a device has or may have caused or contributed to the death of a patient (this includes employees).

Life-threatening - Check if the patient was at risk of dying at the time of the adverse event or if the continued use of the device might have resulted in the death of the patient.

Disability - Check if a device has or may have caused or contributed to a permanent injury or impairment to the patient.

Congenital anomaly - Check if exposure to a medical device prior to conception or during pregnancy has or may have resulted in an adverse outcome in the child.

Required intervention to prevent permanent impairment or damage - Check if medical or surgical intervention was necessary to preclude permanent impairment of a body function or to prevent permanent damage to a body structure that was or may have been due to the use of a medical device.

SECTION B - ADVERSE EVENT OR PRODUCT PROBLEM - BLOCK B2 (continued)

Other - Check only if the other categories are not applicable to the event. Briefly describe the patient outcome in the space provided. The actual narrative of the event will be entered in block B5.

B3: **Date of event** - Provide the actual or best estimate of the date of first onset of the adverse event. For congenital anomalies, the date of birth or the date pregnancy is terminated should be used. If day is unknown, month and year are acceptable. If day and month are unknown, year is acceptable.

B4: **Date of report** - The date the initial reporter provided the information about the event (i.e. the first person or entity who initially provided the information to the user facility, manufacturer or distributor).

B5: **Describe event or problem**:

Adverse event - Describe the event in detail. Include a description of the nature of the event, how the device was involved, any environmental conditions that may have influenced the event, patient follow-up or required treatment (e.g. relevant clinical information, medical status prior to the event, signs, symptoms, diagnoses, clinical course, treatment, outcome, etc.). If available, and if relevant, include synopses of any office visit notes or the hospital discharge summary. If permitted by the institution, copies of these records may be attached with any confidential information deleted. **DO NOT identify any patient, physician or institution by name. The initial reporter's identity should be provided in full in section E.** Enter results of relevant tests and laboratory data in block B6 and preexisting medical conditions and other relevant history in block B7.

Product Problem - Describe the problem and the circumstances surrounding the defect or malfunction of the medical device. The results of any evaluation of the malfunctioning device and, if known, any relevant maintenance/service information should be included in this section.

B6: **Relevant tests/laboratory data, including dates** - Include any relevant baseline laboratory data prior to the administration or use of the medical device, all laboratory data used in diagnosing the event and any available laboratory data/engineering analyses that provide further information on the course of the event. Include any available pre and post-event medication levels and dates if applicable. Include synopses of any relevant autopsy, pathology, engineering or lab reports, if available. If preferred, copies of any reports may be submitted as attachments with all confidential information deleted. **DO NOT identify any patient, physician or institution by name. The initial reporter's identity should be provided in full in section E**.

B7: **Other relevant history, including preexisting medical conditions -** If relevant, provide information on other known conditions in the patient (e.g. hypertension, diabetes, renal/hepatic dysfunction, etc.) and significant history (e.g. allergies, race or ethnic origin, pregnancy, smoking and alcohol use, drug abuse, etc.).

SECTION C: SUSPECT MEDICATION(s)

This section is intended to be used when reporting adverse events associated with the use of suspect medications.

C1 - C10: **Skip - Not intended for medical device use.**

SECTION D: SUSPECT MEDICAL DEVICE

The suspect medical device is the device that may have caused or contributed to the adverse event or the device that malfunctioned. If more than one suspect medical device was involved in the event, complete all of sections D and F for the first device and a separate section D and blocks F9, F10, F13, and F14 for each additional device. Pair each section D with it's corresponding section F by marking each as follows: "Device 1", "Device 2", etc.

D1: **Brand name** - The trade or proprietary name of the suspect medical device as used in product labeling or in the catalog. (e.g. Flo-Easy Catheter, Reliable Heart Pacemaker, etc.). This information may be on a label attached to a durable device, may be on a package of a disposable device, or may appear in labeling materials of an implantable device.

D2: **Type of device** - The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.).

D3: **Manufacturer name & address** - If available, list the full name and mailing address of the manufacturer of the suspect medical device.

D4: **Operator of device** - Indicate the type (**not the name**) of person operating or using the suspect medical device on the patient at the time of the event.

Health professional	=	physician, nurse, respiratory therapist, etc.
Lay user/patient	=	person being treated, parent/spouse/friend of patient.
Other	=	Nurse's aide, orderly, etc.

D5: **Expiration date** - If applicable. This date can often be found on the device itself or printed on the accompanying package.

D6: **Product identification numbers** - If available. Provide any or all identification numbers associated with the suspect medical device exactly as they appear on the device or device labeling.

Model # - The exact model number found on device label or accompanying packaging.

Catalog # - The exact catalog number as it appears in the manufacturer's catalog, device labeling or accompanying packaging.

Serial # - Can be found on device label or accompanying packaging. This number, assigned by the manufacturer should be specific to each device.

SECTION D: SUSPECT MEDICAL DEVICE - BLOCK D6 (continued)

Lot # - Can be found on the label or packaging material.

Other # - Any other applicable identification number (e.g. component number, product number, part number, barcoded product ID, etc.).

D7: **If implanted, give date** - For medical devices that are implanted in the patient, provide the implant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.

D8: **If explanted, give date** - If an implanted device was removed from the patient, provide the explant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.

D9: **Device available for evaluation?** - Indicate whether the device is available for evaluation. Indicate if the device was returned to the manufacturer and if so, the date of the return. (**DO NOT send the device to FDA**).

D10: **Concomitant medical products and therapy dates** - List and provide device product names and therapy dates for any other medical devices that were being used on a patient at the time of the event. (**DO NOT include products used to treat the event**).

SECTION E: INITIAL REPORTER

Indicate the person who initially provided information about the event to the user facility, manufacturer or distributor. For user facilities, this person may or may not be the designated medical device reporting (MDR) contact.

E1: **Name, address & phone #** - Please provide the name, mailing address and phone number of the first person or entity that provided the information to the user facility, manufacturer or distributor.

E2: **Health professional?** - Indicate whether the initial reporter is a health professional (e.g. physician, pharmacist, nurse, etc.) or not.

E3: **Occupation** - Indicate the initial reporter's occupation, and include specialty if appropriate.

E4: **Initial reporter also sent report to FDA** - Indicate whether the initial reporter also notified or submitted a copy of this report to FDA.

SECTION F: FOR USE BY USER FACILITY/DISTRIBUTOR - DEVICES ONLY

F1: **Check one** - Indicate whether the report is from a user facility or distributor.

F2: **UF/Dist report number** - Enter the complete number of the report exactly as entered in the upper right corner of the front page.

SECTION F: FOR USE BY USER FACILITY/DISTRIBUTOR - DEVICES ONLY

F3: **User facility or distributor name/address** - Enter the full name and address of the user facility or distributor reporting site.

F4: **Contact person** - Enter the full name of the medical device reporting (MDR) contact person. This is the person designated by the facility's most responsible person as the device user facility/distributor contact for this requirement. FDA will conduct its MDR correspondence with this individual. The contact person may or may not be an employee of the facility. However, the facility and its responsible officials will remain the parties ultimately responsible for compliance with MDR reporting requirements.

F5: **Phone number** - Enter the phone number of the medical device reporting (MDR) contact person.

F6: **Date user facility or distributor became aware of event** - Enter the date that the user facility's medical personnel or the distributor became aware that the device may have caused or contributed to the reported event.

F7: **Type of report** - Check the appropriate box to identify the type of report being filed.

If a follow-up report, make sure that the UF/Dist report number for the previously submitted initial report is recorded in block F2. In the blank provided in block F7, record the appropriate sequence of follow-up to that particular initial report (e.g. first follow-up report = follow-up #1, second follow-up report = follow-up # 2, etc.). Follow-up reports should not repeat material that was submitted in the initial report but should only provide additional or corrected information.

F8: **Date of this report** - Enter the date that the report was forwarded to the manufacturer and/or the FDA.

F9: **Approximate age of device** - Enter the age of the device or a best estimate. (Include unit of time used, e.g. month, year).

F10: **Event problem codes** - Enter up to 3 "patient" and 3 "device" codes from the coding manual (See Part I) that most accurately describe the event. Patient codes describe what happened to the patient as a result of the event and device codes describe device failures or problems during the event. If more than 3 "patient" codes or more than 3 "device" codes are needed, record them on a separate sheet, mark it "F10" and provide the report number and page number.

F11: **Report sent to FDA?** - Check "yes" or "no" and indicate the date sent, if applicable.

F12: **Location where event occurred** - Check the location of the actual occurrence of the event. If none of the designated location options apply, check the "other" box and provide the location.

F13: **Report sent to manufacturer?** - Check "yes" or "no" and indicate the date sent, if applicable. Reports must be sent to the manufacturer if the manufacturer is known.

F14: **Manufacturer name/address** - Enter full name and address of the device manufacturer, if available.

SECTION G: ALL MANUFACTURERS

G1: **Contact office - name/address(& mfring site for devices)** - Enter the full name and address of the manufacturer reporting site [contact office] including contact name. If the manufacturing site is different than the contact office, enter "Site:" and the name and address of that site.

G2: **Phone number** - Enter the telephone number of the contact office.

G3: **Report source** - Check the box(s) that most accurately describes how the manufacturer [contact office] became aware of the reported adverse event or where the information about the adverse event came from.

Foreign - Foreign sources include foreign governments, foreign medical facilities, etc.

Study - Postmarketing, clinical trial, surveillance, or other study which involves a systematic collection of adverse events from a protocol designed specifically to investigate product safety. Check this box when reporting on required postmarket and discretionary postmarket studies under Section 522 of the FD&C Act.

Literature - If the report source is the scientific literature or an unpublished manuscript, then attach a copy of the article or manuscript, in English. Record the date of the article as the date of the event (block B3), and provide a full literature citation in block H10.

Consumer - (including attorneys) - Generally, additional information should be sought from the treating health care provider. A determined effort should be made to obtain additional detailed information from health professionals for all events initially reported by consumers. When this additional information is obtained, the follow-up report should check health professional rather than consumer.

Health professional - self explanatory.

User facility - self explanatory.

Company representative - Check if the company representative reported the event to the contact office based on information from a health professional. The health professional should be listed as the initial reporter in section E.

Distributor - Distributor should be checked if the manufacturer received the report from a distributor of the suspect medical device.

Other - Check if none of the available options is appropriate and specify source.

G4: **Date received by manufacturer** - This is the date when the manufacturer became aware of information that an adverse event or medical device malfunction occurred. This would apply anywhere in the world. For follow-up (i.e. supplemental) reports, use the date that the follow-up (supplemental) information was received.

G5: **Skip - Not intended for medical device reports**.

SECTION G: ALL MANUFACTURERS (continued)

G6: **Skip - Not intended for medical device reports**.

G7: **Type of report**:

"5-day" - Check if submitting a 5-day report.

"Initial" - Check if first or initial submission of a 5-day or 30-day report.

"Periodic" - Not intended for medical device reports.

"Follow-up (i.e. supplemental) #" - Check if follow-up (supplemental) submission. The manufacturer report number for the previously submitted initial report is recorded in block G9. In the blank provided in block G7 after "follow-up", record the appropriate sequence of follow-up (supplement) to that particular initial report (e.g. first follow-up (supplemental) report = follow-up #1, second follow-up (supplemental) report = follow-up # 2, etc). Follow-up (supplemental) reports should not repeat any information that was submitted in the initial report, but should only provide additional or corrected information.

G8: **Skip - Not intended for medical device reports.**

G9: **Mfr. report number** - Enter the manufacturer report number exactly as it appears in the upper right corner of the front page. For a follow-up (supplemental) report the manufacturer report number is to be identical to the number assigned to the initial report.

SECTION H: DEVICE MANUFACTURERS ONLY

H1: **Type of reportable event** - Check the appropriate box. These choices represent the categories of events that device manufacturers are required to report. ("See guidelines" refers to the applicable sections in 21 CFR Part 803 reporting guidelines associated with device malfunctions).

Other - Specify the type of report in the space provided. This option is intended to capture reports that a manufacturer believes the agency should be aware of that are not covered by death, serious injury, or malfunction as these terms are defined by the statute, regulation or guidelines.

H2: **If follow-up (supplemental) report, what type?** - Check the box(s) that most accurately describes the nature of the follow-up (supplemental) report.

Correction - Changes to previously submitted information.

Additional information - Information concerning the event that was not provided in the initial report because it was not known/available when the report was originally submitted.

Response to FDA request - Additional information requested by FDA concerning the device/event.

Device evaluation - Evaluation/analysis of device.

SECTION H: DEVICE MANUFACTURERS ONLY (continued)

H3: **Device evaluated by mfr?** - Check the box marked "not returned to mfr." if an evaluation could not be made because the device was not returned to or made available to the manufacturer. Check the box marked "yes" if an evaluation was made of the suspect or related medical device. If an evaluation was conducted attach a summary of the evaluation and check the box marked "evaluation summary attached". If an evaluation of a returned suspect or related medical device was not conducted, check the box marked "no" and attach a page to explain why not or provide the appropriate code from the coding manual (Part II, Subpart A) in the space provided.

H4: **Device manufacture date** - Enter the month and year of manufacture of the suspect medical device using a MM/YYYY date format.

H5: **Labeled for single use?** - Indicate whether the device was labeled for single use or not. If the question is not relevant to the device being reported, (e.g. an x-ray machine), check "no".

H6: **Evaluation codes** - Enter the applicable codes from the coding manual (See Part II, Subpart B) for one or more of the categories listed. Conclusion codes must be entered even if the device was not evaluated.

H7: **If remedial action initiated, check type** - Indicate the applicable actions(s). If other, specify the type of action in the space provided. Most of these terms are defined or further explained in the Act or in the FDA regulations concerning remedial action (see 21 U.S.C. 360h and 21 CFR part 803).

H8: **Usage of device** - Indicate whether the use of the suspect medical device was the initial use, reuse or unknown.

H9: **If action reported to FDA under 21 U.S.C. 360i(f), list correction/removal reporting number** Enter the number that FDA assigned to the corrective action. If a number has not yet been assigned by FDA, the internal number assigned by the firm for the action may be used.

H10: **Additional manufacturer narrative** - Enter any additional information, evaluation, or clarification of data presented in previous sections. Do not duplicate information that has already been provided elsewhere.

SECTION H: DEVICE MANUFACTURERS ONLY (continued)

H11: **Corrected data** - Provide the following additional, corrected or missing information, identifying each data item by the applicable section and block number:

(1) any information missing on the user facility or distributor report, including any missing or incomplete event codes required by block F10,

(2) information corrected on the user facility or distributor report form after verification, including any corrected event codes required by block F10,

(3) for each event code provided in block F10, a statement of whether the type of event represented by the code is addressed in the device labeling, e.g., code # 1738 - labeled, code # 1701 - not labeled, and

(4) an explanation of why any required information was not provided and the steps taken to obtain such information.

INSTRUCTIONS FOR USING THE DEVICE CODING MANUAL FOR FORM 3500A

The Device Coding Manual is to be used to fill out certain sections of Form 3500A when reporting adverse events and product problems associated with the use of medical devices. It has been divided into two parts. Part 1 is to be used by User Facilities when filling out Section F, block F10 of the form, and Part 2 is to be used by Device Manufacturers when filling out Section H, blocks H3 and H6 of the form. When entering the applicable codes, place one entire code per box, not one digit per box. Instructions for using each part are detailed below.

PART I - EVENT PROBLEM CODES AND TERMS (For Section F, Block F10 of Form 3500A)

This part contains patient- and device-related event terms and corresponding event codes that, when selected, will best describe what happened to the patient as a result of the event or the device failure or problem at the time of the event. At least one code should be selected for patient and/or device. If more than 3 codes are needed for either category, a supplemental page containing those additional codes, may be attached following the general instructions for completing form 3500A. In order to make this part more flexible, it has been divided into three subparts, A, B and C.

SUBPART A - ALPHABETIC LISTING OF EVENT TERMS WITH THEIR CORRESPONDING EVENT CODE

This subpart is divided into two lists. One list contains patient-related event terms and the other device-related event terms. Each list is alphabetically ordered by event term with its corresponding numeric event code.

SUBPART B - NUMERIC LISTING OF EVENT CODES WITH THEIR CORRESPONDING EVENT TERM

This subpart contains a list of all patient- and device-related event terms, numerically ordered by event code.

SUBPART C - DEFINITIONS FOR EVENT TERMS LISTED NUMERICALLY BY EVENT CODE

This subpart contains a glossary of all patient- and device-related event terms that are not self-explanatory, and is intended to be used as a reference guide for Subpart A. Only one list is provided in this part with both patient- and device-related event term definitions ordered numerically by event code.

PART II - DEVICE MANUFACTURER CODES (For Section H, Blocks H3 and H6 of Form 3500A)

This part contains the codes that are to be used by Device Manufacturers when reporting the results of their evaluation of the suspect or related medical device. The evaluation codes for this part have been divided into two subparts, A and B. The sections within each subpart, are alphabetically ordered by evaluation term with its corresponding numeric evaluation code.

PART II - DEVICE MANUFACTURER CODES (For Section H, Blocks H3 and H6 of Form 3500 A) (continued)

SUBPART A - DEVICE EVALUATED BY MANUFACTURER (Block H3)

The codes from this section are designed to be used when the device was not evaluated. The codes selected should indicate why no evaluation was performed.

SUBPART B - EVALUATION CODES (Block H6)

The codes from this section are divided into three groups, Method of Evaluation, Results of Evaluation and Conclusions. When entering the applicable codes, place one entire code per box, not one digit per box. Select only those evaluation codes that best identify the primary contributing factors. Four boxes for each group have been provided for your codes, however, if more are needed, a supplemental page may be attached following the general instructions for completing form 3500A. Indicate the appropriate section and block number and the additional codes.

METHOD OF EVALUATION CODES

There are two lists in this group, one to indicate the source of the device evaluated and the other to indicate the type of evaluation performed. At least one code from each of the two lists should be selected.

RESULTS OF EVALUATION CODES

There are five categories in this group. The first three, A, B and C are broad characterizations of what the evaluation found. The second two, D and E are very specific in nature.

Select one or more codes from at least one of the first three categories. You may select codes from more than one category, if applicable.

Category A - Device
Category B - Use of Device
Category C - Physiological/Procedural Factors

When the result involves component failures and computer related problems, select as many of the applicable codes as needed from the following categories and enter them on the same line:

Category D - Device Component/Subassembly Failures
Category E - Computer-, Imaging System-, Microprocessor-Controlled Device Problems

CONCLUSIONS CODES

In this group, select the code(s) that best describe your conclusions.

IMPORTANT REFERENCE INFORMATION AND MAILING ADDRESSES

HOW TO OBTAIN COPIES OF FDA FORM 3500A AND INSTRUCTIONS FOR COMPLETING FORM 3500A WITH THE DEVICE CODING MANUAL:

Bulk copies of FDA Form 3500A can be obtained from:

Consolidated Forms and Publications Distribution Center
Washington Commerce Center
3222 Hubbard Road
Landover, Maryland 20785

Ten copies or less of the form and/or copies of the "Instructions for Completing Form 3500A with the Device Coding Manual for Form FDA 3500A" can be obtained from:

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Fax number: 301-443-8818

DSMA FACTS-ON-DEMAND fax number: 1-800-899-0381 or 301-827-0111.

Copies of a blank FDA Form 3500A may be duplicated by the applicant.

The "Instructions for Completing Form 3500A with the Device Coding Manual for Form 3500A" are also available through the Center for Devices and Radiological Health's (CDRH) Electronic Docket/Home Page at:

Via modem: 1-800-252-1366, 301-594-2741 or 1-800-222-0185

Telnet Access Via Internet = fedworld.gov (192.239.92.3)

World Wide Web (Home Page) = www.fda.gov/cdrh/cdrhhome.html (this is the URL)

FOR APPROVAL OF COMPUTER-GENERATED FACSIMILES OF 3500A, CONTACT:

MEDWATCH: The FDA Medical Products Reporting Program
Office of the Commissioner HF-2
Food and Drug Administration, Rm. 9-57
5600 Fishers Lane
Rockville, MD 20857

SEND COMPLETED FORM 3500A TO:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
P.O. Box 3002
Rockville, MD 20847-3002

Each envelope containing a completed Form 3500A should be specifically identified as a "User Facility Report", "Distributor Report", "Manufacturer Report", "Five-Day Report", etc.

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See OMB statement on reverse

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Page ___ of ___

Mfr report #

UF/Dist report #

FDA Use Only

A. Patient information

1. **Patient identifier** In confidence

2. **Age at time of event:** or **Date of birth:**

3. **Sex** ☐ female ☐ male

4. **Weight** ___ lbs or ___ kgs

B. Adverse event or product problem

1. ☐ **Adverse event** and/or ☐ **Product problem** (e.g., defects/malfunctions)

2. **Outcomes attributed to adverse event** (check all that apply)
   - ☐ death ___ (mo/day/yr)
   - ☐ life-threatening
   - ☐ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other: ___

3. **Date of event** (mo/day/yr)

4. **Date of this report** (mo/day/yr)

5. **Describe event or problem**

6. **Relevant tests/laboratory data**, including dates

7. **Other relevant history, including preexisting medical conditions** (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. **Name** (give labeled strength & mfr/labeler, if known)
   #1
   #2

2. **Dose, frequency & route used**
   #1
   #2

3. **Therapy dates** (if unknown, give duration) from/to (or best estimate)
   #1
   #2

4. **Diagnosis for use** (indication)
   #1
   #2

5. **Event abated after use stopped or dose reduced**
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply

6. **Lot #** (if known)
   #1
   #2

7. **Exp. date** (if known)
   #1
   #2

8. **Event reappeared after reintroduction**
   #1 ☐ yes ☐ no ☐ doesn't apply
   #2 ☐ yes ☐ no ☐ doesn't apply

9. **NDC #** – for product problems only (if known)
   – –

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

D. Suspect medical device

1. **Brand name**

2. **Type of device**

3. **Manufacturer name & address**

4. **Operator of device**
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other: ___

5. **Expiration date** (mo/day/yr)

6.
   model # ___
   catalog # ___
   serial # ___
   lot # ___
   other # ___

7. **If implanted, give date** (mo/day/yr)

8. **If explanted, give date** (mo/day/yr)

9. **Device available for evaluation?** (Do not send to FDA)
   ☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. **Concomitant medical products** and therapy dates (exclude treatment of event)

E. Initial reporter

1. **Name, address & phone #**

2. **Health professional?** ☐ yes ☐ no

3. **Occupation**

4. **Initial reporter also sent report to FDA** ☐ yes ☐ no ☐ unk

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

FDA Form 3500A (6/93)

Medication and Device Experience Report
(continued)

Refer to guidelines for specific instructions

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service • Food and Drug Administration

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FDA Use Only

F. For use by user facility/distributor–devices only

1. **Check one**
☐ user facility ☐ distributor

2. **UF/Dist report number**

3. **User facility or distributor name/address**

4. **Contact person**

5. **Phone Number**

6. **Date user facility or distributor became aware of event** (mo/day/yr)

7. **Type of report**
☐ initial
☐ follow-up # ____

8. **Date of this report** (mo/day/yr)

9. **Approximate age of device**

10. **Event problem codes** (refer to coding manual)
patient code ____ – ____ – ____
device code ____ – ____ – ____

11. **Report sent to FDA?**
☐ yes ____ (mo/day/yr)
☐ no

12. **Location where event occurred**
☐ hospital
☐ home
☐ nursing home
☐ outpatient treatment facility
☐ outpatient diagnostic facility
☐ ambulatory surgical facility
☐ other: ____ specify

13. **Report sent to manufacturer?**
☐ yes ____ (mo/day/yr)
☐ no

14. **Manufacturer name/address**

G. All manufacturers

1. **Contact office – name/address** (& mfring site for devices)

2. **Phone number**

3. **Report source** (check all that apply)
☐ foreign
☐ study
☐ literature
☐ consumer
☐ health professional
☐ user facility
☐ company representative
☐ distributor
☐ other: ____

4. **Date received by manufacturer** (mo/day/yr)

5. (A) NDA # ____
IND # ____
PLA # ____
pre-1938 ☐ yes
OTC product ☐ yes

6. **If IND, protocol #**

7. **Type of report** (check all that apply)
☐ 5-day ☐ 15-day
☐ 10-day ☐ periodic
☐ Initial ☐ follow-up # ____

8. **Adverse event term(s)**

9. **Mfr. report number**

H. Device manufacturers only

1. **Type of reportable event**
☐ death
☐ serious injury
☐ malfunction (see guidelines)
☐ other: ____

2. **If follow-up, what type?**
☐ correction
☐ additional information
☐ response to FDA request
☐ device evaluation

3. **Device evaluated by mfr?**
☐ not returned to mfr.
☐ yes ☐ evaluation summary attached
☐ no (attach page to explain why not) or provide code: ____

4. **Device manufacture date** (mo/yr)

5. **Labeled for single use?**
☐ yes ☐ no

6. **Evaluation codes** (refer to coding manual)
method ____ – ____ – ____ – ____
results ____ – ____ – ____ – ____
conclusions ____ – ____ – ____ – ____

7. **If remedial action initiated, check type**
☐ recall
☐ repair
☐ replace
☐ relabeling
☐ other: ____
☐ notification
☐ inspection
☐ patient monitoring
☐ modification/ adjustment

8. **Usage of device**
☐ initial use of device
☐ reuse
☐ unknown

9. If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number:

10. ☐ **Additional manufacturer narrative** and/or 11. ☐ **Corrected data**

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PART I, SUBPART A - ALPHABETIC LISTING OF EVENT TERMS WITH THEIR CORRESPONDING NUMERIC EVENT CODE

PATIENT-RELATED TERMS

1685 Abdominal pain
1034 Abnormal blood gas measurements
2370 Abnormal mammogram
2078 Abnormality of ventricle
1688 Abortion
2211 Abortion, artificial
2212 Abortion, complete
2213 Abortion, incomplete
2214 Abortion, induced
2215 Abortion, missed
2216 Abortion, therapeutic
1689 Abrasion
1789 Abrasion, corneal
1690 Abscess
2261 Absence seizures
1945 Acanthamoeba keratitis
1770 Accident (CVA), cerebrovascular
1692 Achalasia
2482 Acidosis, respiratory
1693 Acoustic shock
1694 Acoustic trauma
1684 Acquired immunodeficiency syndrome, (AIDS)
2269 Acquired toxoplasmosis
1695 Adhesion(s)
1696 Adult respiratory distress syndrome, (ARDS)
1684 AIDS, acquired immunodeficiency syndrome
1697 Air embolism
1698 Airflow, restricted
1699 Airway obstruction
2483 Alkalosis, respiratory
1701 Allergic reaction
2217 Amnionitis
1702 Amputation
2015 ANA, positive antinuclear antibodies
1703 Anaphylactic shock
2218 Anaphylactoid
1704 Anaphylaxis
1028 Anastomose, failure to
1705 Anastomosis
1706 Anemia
2279 Anemia, hemolytic
1707 Anesthesia, insufficient, light or patchy
1708 Aneurysm
1710 Angina
1711 Anoxia
1713 Antibiotics, reaction to
2015 Antibodies (ANA), positive antinuclear
1714 Anticoagulation
2015 Antinuclear antibodies (ANA), positive
2328 Anxiety
1715 Aortic insufficiency
1716 Aortic regurgitation
1717 Aortic stenosis
2472 Aortic valve replacement
1805 Apgar, decreased
1718 Apgar score, decreased or low
1719 Apheresis
2372 Apicectomy
1720 Apnea
2390 Arachnoiditis, spinal
1696 ARDS, adult respiratory distress syndrome
2351 Arm fracture
2353 Arm/hand hypoesthesia
1762 Arrest, cardiac
1765 Arrest, cardiopulmonary
2044 Arrest, respiratory
1721 Arrhythmia
2480 Arterial wedge pressure, high pulmonary
2479 Arterial wedge pressure, low pulmonary
2481 Arterial wedge pressure, normal pulmonary
1722 Arteriosclerosis
2355 Arthralgia
1723 Arthritis
1724 Arthritis, rheumatoid
2211 Artificial abortion
1851 Asphyxia
2209 Asphyxia, fetal
1725 Aspiration
1726 Asthma
1727 Asystole
1728 Atherosclerosis
1729 Atrial fibrillation
1730 Atrial flutter
1731 Atrial tachycardia
2109 Attack, transient ischemic
2058 Aureus, staphylococcus
1732 Autoimmune disease
1733 Autoimmune reaction
1735 Bacterial infection
1736 Biliary cirrhosis
1738 Bleeding
1739 Bleeding, cerebral
1741 Bleeding, intracranial
1742 Blindness
2229 Blinking, excessive
1743 Blister(s)
1744 Bloating
2026 Block, pupillary
2332 Blockage
1034 Blood gas measurements, abnormal
2451 Blood glucose, high
2450 Blood glucose, low
2143 Blood in vitreous fluid
1747 Blood pooling
2488 Blood pressure, high
2489 Blood pressure, low

PATIENT-RELATED TERMS (continued)

2337 Blood products, transfusion of
2025 Blood vessels, punctured
1749 Blood, transfusion with incompatible
1745 Blood/fluids, contamination from
2137 Blurred vision
2230 Blurring
2461 Body temperature, decreased
2096 Body temperature, elevated
1803 Bone shedding debris
1756 Bowel burn
1751 Bradycardia
2394 Brain damage
2219 Brain injury
1852 Brain injury, fetal
1388 Breakage of membrane
2106 Breakdown of optical tissue
1759 Breast cancer
2439 Breast lumps
2438 Breast neoplasm
2401 Breathing difficulties
1593 Breaths, stacking
1752 Bronchitis
2437 Bronchopneumonia
1754 Bruise
1757 Burn(s)
1756 Burn, bowel
1755 Burn, radiation
2146 Burning sensation
1774 C-section (cesarean section), delivery by
1758 Calcification
2147 Calcium deposit(s)
1759 Cancer, breast
1760 Cancer, other
1761 Capsular contracture
1551 Capsular contracture, rupture due to stress from
1762 Cardiac arrest
1763 Cardiac contusion
1838 Cardiac enzyme elevation
2334 Cardiac insufficiency
2226 Cardiac tamponade
2262 Cardiogenic shock
1764 Cardiomyopathy
1765 Cardiopulmonary arrest
1766 Cataract
1767 Cataract, induced
1768 Cellulitis
2228 Central corneal clouding
1739 Cerebral bleeding
1889 Cerebral hemorrhage
1771 Cerebral, infarction
1772 Cerebrospinal fluid leakage
1770 Cerebrovascular accident, (CVA)
1773 Cervical changes
1927 Cervix, incompetent
1774 Cesarean section (c-section)
1817 Changes in EKG/ECG
2162 Changes in/loss of nipple sensation
1773 Changes, cervical
1831 Changes, emotional
2455 Chemical contamination
1775 Chemosis
1776 Chest pain
2463 Chest tightness/pressure
2098 Children, toxins in
2191 Chills
2464 Choking
1777 Chorioamnionitis
2237 Chronic obstructive pulmonary disease, (COPD)
2060 Cicatrix
1736 Cirrhosis, biliary
2222 Clonic convulsion
2228 Clouding, central corneal
2220 CMV, cytomegalovirus
1778 Coagulation
1813 Coagulation (DIC), disseminated intravascular
1779 Coagulopathy
2189 Collagen disease
2416 Collapse
2417 Coma
1781 Comatose
2331 Complaint, ill-defined
2212 Complete abortion
2192 Concussion
2155 Condition of patient, improved
1782 Congenital defect/deformity
2270 Congenital toxoplasmosis
1783 Congestive heart failure
1784 Conjunctivitis
1785 Conjunctivitis, giant papillary
1786 Connective tissue disease
2418 Consciousness, loss of
2199 Consequences or impact to patient, none
1745 Contamination from blood/fluids
2455 Contamination, chemical
1761 Contracture, capsular
1125 Contraindicated patient
1787 Contusion
1763 Contusion, cardiac
1953 Contusion, liver
1763 Contusion, myocardial
2221 Convulsion
2222 Convulsion, clonic
2223 Convulsion, tonic
2237 COPD, chronic obstructive pulmonary disease
1788 Core temperature rise
1854 Core temperature rise, fetal
1792 Cornea, perforation of
1789 Corneal abrasion
2228 Corneal clouding, central
1790 Corneal decompensation
1791 Corneal edema
2173 Corneal implant
2231 Corneal infiltrates

PATIENT-RELATED TERMS (continued)

1793 Corneal scar
2233 Corneal sensitivity
1794 Corneal touch
1795 Corneal transplant
1796 Corneal ulcer
2193 Cramp(s)
1797 Crushing injury
2453 Cut(s)
1417 Cuts, nicks or tears of dura or other tissues by device
1770 CVA, cerebrovascular accident
1798 Cyanosis
1799 Cyclitis
1800 Cyst(s), formation of
1957 Cytomegaloviral retinitis
2220 Cytomegalovirus (CVM)
1952 Damage to ligament(s)
1979 Damage to nerve(s)
1981 Damage to neural tissue
1986 Damage to optical nerve(s)
2048 Damage to retina
2394 Damage, brain
2104 Damage, tissue
2124 Damage, vaginal mucosa
1801 Deafness
1855 Death, intrauterine fetal
1802 Death/expired
1803 Debris, bone shedding
1790 Decompensation, corneal
1805 Decreased apgar
2461 Decreased body temperature
2430 Decreased forced expiratory volume (FEV)
1718 Decreased or low apgar score
2435 Decreased peak expiratory flowrate
2485 Decreased respiratory rate
2271 Decreased therapeutic response
1782 Defect/deformity, congenital
1982 Deficit/dysfunction, neurological
1974 Deformities, neonatal
1782 Deformity/defect, congenital
1806 Degeneration
2049 Degeneration of retina
1154 Dehiscence wound
1807 Dehydrated
1156 Delamination
2369 Delayed union fracture
1936 Delayed, uncontrolled intraocular pressure (IOP)
1774 Delivery by cesarean section (c-section)
1808 Dementia
2224 Dementia, dialysis
2395 Dependent, ventilator
2147 Deposit(s), calcium
1809 Deposits
2361 Depression
2487 Depression, ST segment
2253 Dermatomyositis
2047 Detached retina
2445 Detachment of vitreous
1204 Device embedded in vessel or plaque
1810 Device induced
2364 Diabetic ketoacidosis
2406 Diagnosis, identified
2224 Dialysis dementia
2452 Diaphoretic
1811 Diarrhea
1813 DIC, disseminated intravascular coagulation
2401 Difficulty breathing
2070 Digits (finger or toe), severed
2244 Direct infection
2371 Disability
2225 Discharge
1812 Discharge, purulent
2123 Discharge, vaginal
2074 Discoloration of skin
2330 Discomfort
2237 Disease (COPD), chronic obstructive pulmonary
2039 Disease (ESRD), end stage renal
2000 Disease (PID), pelvic inflammatory
2071 Disease (VD), venereal
1732 Disease, autoimmune
2189 Disease, collagen
1786 Disease, connective tissue
2002 Disease, peripheral vascular
2053 Disease, rheumatic heart
2360 Disfigurement
2374 Dislocated joint
2373 Disorder, joint
1353 Disruption, leaflet
1333 Dissection, intimal
1813 Disseminated intravascular coagulation (DIC)
1826 Dissociation, electro-mechanical
2329 Distress
1856 Distress, fetal
2045 Distress, respiratory
2140 Disturbances, visual
2194 Dizziness
1814 Dry eye(s)
1417 Dura nicks, cuts or tears by device
1947 Dysfunction, left ventricular
1954 Dysfunction, liver
2019 Dysfunction, pulmonary
2054 Dysfunction, right ventricular
1982 Dysfunction/deficit, neurological
2363 Dyskinesia
1815 Dysphagia
2195 Dysphasia
1816 Dyspnea
2103 Ears, ringing in
1818 Ecchymosis
1817 ECG/EKG changes
1819 Ectopic pregnancy
1820 Edema

PATIENT-RELATED TERMS (continued)

1791 Edema, corneal
1822 Edema, macular
1823 Edema, microcytic
2020 Edema, pulmonary
1824 Edema, stromal
2273 Effects, teratogenic
2099 Effects, unexpected therapeutic
2010 Effusion, pleural
1817 EKG/ECG changes
1826 Electro-mechanical dissociation
1827 Electrocution
2196 Electrolyte imbalance
2096 Elevated body temperature
1838 Elevation of cardiac enzymes
2059 Elevation, ST segment
1829 Embolism
1697 Embolism, air
1498 Embolism, pulmonary
1830 Embolus
1831 Emotional changes
1832 Emphysema, pulmonary
2429 Encephalitis
1833 Encephalopathy
2039 End stage renal disease (ESRD)
1834 Endocarditis
1835 Endophthalmitis
2236 Endotoxin
2327 Entrapment
1838 Enzyme elevation, cardiac
2150 Epithelial marsupialization
2232 Epithelial microcysts
1750 Erosion
2013 Erosion, pocket
2075 Erosion, skin
1839 Eructate
1840 Erythema
2398 Esophagus, laceration(s) of
2399 Esophagus, perforation of
2039 ESRD, end stage renal disease
2229 Excessive blinking
2235 Excessive tearing
2358 Excision, scar
1843 Exhaustion, extreme
1802 Expired/death
1841 Exsanguination
1890 Extradural hemorrhage
1842 Extravasation
1843 Extreme exhaustion
1844 Extrusion
2402 Extubate
1845 Eye injury
1814 Eye(s), dry
2038 Eye(s), red
1901 Face, rupture of hyaloid
1846 Facial nerve paralysis
1924 Failure of implant
1028 Failure to anastomose
1783 Failure, congestive heart
2206 Failure, heart
1948 Failure, left ventricular
2041 Failure, renal
2484 Failure, respiratory
2055 Failure, right ventricular
2105 Failure, tissue
1610 Faint
1847 Fainting
1848 Fall
2375 Fasciitis
1849 Fatigue
1850 Feeding problems
2209 Fetal asphyxia
1852 Fetal brain injury
1854 Fetal core temperature rise
1855 Fetal death, intrauterine
1856 Fetal distress
2210 Fetal hypoxia
1857 Fetal scalp laceration(s)
2430 FEV (forced expiratory volume), decreased
2431 FEV, (forced expiratory volume), increased
1858 Fever
1859 Fiberoptic fragments, unretrieved in body
1729 Fibrillation, atrial
2130 Fibrillation, ventricular
1860 Fibromyitis
1861 Fibrosis
2070 Finger or toe, severed
2239 First use syndrome
1862 Fistula
1972 Flap tissue, necrosis of
1864 Flashers
2153 Flashes, hot
1865 Flatus
1866 Floaters, vitreous
2052 Flow, retrograde
2435 Flowrate, decreased peak expiratory
2436 Flowrate, increased peak expiratory
2143 Fluid, blood in vitreous
1772 Fluid, leakage of cerebrospinal
2142 Fluid, loss of vitreous
1745 Fluids/blood, contamination from
1730 Flutter, atrial
2131 Flutter, ventricular
2064 Focal motor seizures
2260 Focal seizures
2354 Foot/leg hypoesthesia
2430 Forced expiratory volume (FEV), decreased
2431 Forced expiratory volume (FEV), increased
1868 Foreign body reaction
1869 Foreign body sensation
2365 Foreign body, removal of
1800 Formation of cyst(s)
1447 Formation, pannus
1870 Fracture(s)
2351 Fracture, arm

PATIENT-RELATED TERMS (continued)

2369 Fracture, delayed union
2349 Fracture, hip
2077 Fracture, skull
2428 Fracture, tooth
1859 Fragments unretrieved in body, fiberoptic
2275 Frequency, urinary
2419 Fungal infection
1872 Fungus
1873 Gangrene
1874 Gastritis
1785 Giant papillary conjunctivitis
2092 Glands, swollen
1875 Glaucoma
2451 Glucose, high blood
2450 Glucose, low blood
2168 Grand-mal seizures
1876 Granuloma
2152 Great vessel perforation
1877 Hair loss
2227 Halo
2353 Hand/arm hypoesthesia
1878 Haze
1879 Head injury
1880 Headache
2186 Headache, lumbar puncture
2186 Headache, post spinal
2378 Healing, impaired
1881 Hearing impairment
1975 Hearing impairment, neonatal
1882 Hearing loss
1976 Hearing loss, neonatal
2053 Heart disease, rheumatic
2206 Heart failure
1783 Heart failure, congestive
2476 Heart valve repair
1883 Heartburn
1884 Hematoma
1288 Hemoconcentration
1885 Hemodialysis
1886 Hemolysis
2279 Hemolytic anemia
1887 Hemoptysis
1888 Hemorrhage
1889 Hemorrhage, cerebral
1890 Hemorrhage, extradural
1891 Hemorrhage, intracranial
1892 Hemorrhage, intraventricular
1893 Hemorrhage, subarachnoid
1894 Hemorrhage, subdural
1895 Hemostasis
1896 Hemothorax
1897 Hepatitis
2240 Hernia
1898 Herpes
1899 Hiccups
2451 High blood glucose
2488 High blood pressure
2478 High oxygen saturation
2480 High pulmonary arterial wedge pressure
2349 Hip fracture
2197 HIV, human immunodeficiency virus
1900 Hives
1297 Host-tissue reaction
2153 Hot flashes
2197 Human immunodeficiency virus (HIV)
1901 Hyaloid face, rupture of
1903 Hyperbilirubinemia
1904 Hyperemia
1905 Hyperglycemia
2242 Hypernatremia
1906 Hyperplasia
1907 Hypersensitivity
1908 Hypertension
1909 Hyperthermia
1949 Hypertrophy, left ventricular
2056 Hypertrophy, right ventricular
1910 Hyperventilation
1911 Hyphema
2352 Hypoesthesia
2353 Hypoesthesia, arm/hand
2354 Hypoesthesia, foot/leg
1912 Hypoglycemia
1913 Hypopyon
1914 Hypotension
1915 Hypothermia
1916 Hypoventilation
2243 Hypovolemia
1917 Hypovolemic shock
1918 Hypoxia
2210 Hypoxia, fetal
1922 Iatrogenic lesion
2406 Identified diagnosis
1923 Idioventricular rhythm
2331 Ill-defined complaint
2196 Imbalance, electrolyte
2156 Immuno-deficiency
2199 Impact or consequences to patient, none
2378 Impaired healing
2138 Impaired vision
1975 Impairment to hearing, neonatal
1881 Impairment, hearing
2173 Implant, corneal
1924 Implant, failure of
1925 Impotence
2155 Improved patient condition
2388 Inadequate pain relief
1749 Incompatible blood, transfusion with
1927 Incompetent cervix
2213 Incomplete abortion
1928 Incontinence
2431 Increased forced expiratory volume (FEV)
2436 Increased peak expiratory flowrate
2486 Increased respiratory rate
2272 Increased therapeutic response

PATIENT-RELATED TERMS (continued)

2245 Indirect infection
2214 Induced abortion
1810 Induced by device
1767 Induced cataract
1969 Infarction (MI), myocardial
1771 Infarction, cerebral
2021 Infarction, pulmonary
1930 Infection
1735 Infection, bacterial
2244 Infection, direct
2419 Infection, fungal
2245 Infection, indirect
1933 Infection, intraocular
2446 Infection, post-operative wound
2447 Infection, post-traumatic wound
2246 Infection, pyrogenic
2247 Infection, subclinical
2420 Infection, upper respiratory tract
2120 Infection, urinary tract
2248 Infection, viral
2174 Infiltrates
2231 Infiltrates, corneal
1931 Infiltration
2087 Infiltration, subepithelial
1932 Inflammation
2443 Inflammation of skin
2000 Inflammatory disease (PID), pelvic
2442 Injection site reaction
2348 Injury
2219 Injury to the brain
1797 Injury, crushing
1845 Injury, eye
1852 Injury, fetal brain
1879 Injury, head
2081 Injury, spinal
2432 Injury, spinal cord
1715 Insufficiency, aortic
2334 Insufficiency, cardiac
1963 Insufficiency, mitral
2022 Insufficiency, pulmonary
2111 Insufficiency, tricuspid
1926 Insufficiency, valvular
1707 Insufficient, light or patchy anesthesia
2264 Insulin shock
1333 Intimal dissection
1741 Intracranial bleeding
1891 Intracranial hemorrhage
1933 Intraocular infection
1936 Intraocular pressure (IOP), delayed, uncontrolled
1937 Intraocular pressure rise, (IOPR)
1855 Intrauterine fetal death
1938 Intravasation
1813 Intravascular coagulation (DIC), disseminated
1892 Intraventricular hemorrhage
1936 IOP (intraocular pressure), delayed, uncontrolled
1937 IOPR, intraocular pressure rise
1940 Iritis
2469 Irregular pulse
1959 Irregularities, menstrual
2421 Irritability
1941 Irritation
2076 Irritation of skin
1942 Ischemia
2109 Ischemic attack, transient
1943 Itching
2187 Jaundice
2374 Joint dislocation
2373 Joint disorder
2355 Joint pain
2356 Joint swelling
1944 Keratitis
1945 Keratitis, acanthamoeba
2364 Ketoacidosis, diabetic
2465 Labor, premature
1946 Laceration(s)
2398 Laceration(s) of esophagus
1857 Laceration(s), fetal scalp
1955 Laceration(s), liver
2003 Laceration(s), peritoneal
1341 LAL test (limulus amebocyte lysate)
2366 Laparotomy
1353 Leaflet disruption
2201 Leak(s), perivalvular
1772 Leakage of cerebrospinal fluid
1947 Left ventricular dysfunction
1948 Left ventricular failure
1949 Left ventricular hypertrophy
2354 Leg/foot hypoesthesia
1950 Lesion
1922 Lesion, iatrogenic
1951 Lesions in the target points
1952 Ligament(s), damage to
1707 Light, patchy or insufficient anesthesia
1341 Limulus amebocyte lysate (LAL) test
1953 Liver contusion
1954 Liver dysfunction
1955 Liver laceration(s)
2035 Local reaction
2418 Loss of consciousness
1877 Loss of hair
1882 Loss of hearing
1976 Loss of hearing, neonatal
1958 Loss of memory
2032 Loss of range of motion
2139 Loss of vision
2142 Loss of vitreous fluid
2162 Loss of/changes in nipple sensation
2450 Low blood glucose
2489 Low blood pressure
1718 Low or decreased apgar score
2477 Low oxygen saturation
2479 Low pulmonary arterial wedge pressure

PATIENT-RELATED TERMS (continued)

2186 Lumbar puncture headache
2439 Lumps, breast
2397 Lung, overinflation of
1956 Lupus
2093 Lymph nodes, swollen
1822 Macular edema
2359 Malaise
2370 Mammogram, abnormal
2150 Marsupialization, epithelial
2276 Materials (nonresorbable), unretrieved in body
1034 Measurements, abnormal blood gas
2198 Mediastinal shift
2117 Medication, not under
2014 Megophthalmos
1388 Membrane, breakage of
1958 Memory loss
2389 Meningitis
1959 Menstrual irregularities
1969 MI, myocardial infarction
1960 Microcyst(s)
2232 Microcysts, epithelial
1823 Microcytic edema
1961 Microperforation(s)
2249 Migration
1962 Miscarriage
2159 Misdiagnosis
2215 Missed abortion
1963 Mitral insufficiency
1964 Mitral regurgitation
1965 Mitral stenosis
2471 Mitral valve prolapse
2376 Mitral valve replacement
2032 Motion, loss of range of
2124 Mucosa damage, vaginal
1966 Muscle spasm(s)
1412 Muscle stimulation
1967 Muscle weakness
1968 Muscular rigidity
2161 Muscular tics
2238 Myalgia
1763 Myocardial contusion
1969 Myocardial infarction, (MI)
2470 Myocarditis
2466 Nasal obstruction
1970 Nausea
2433 Neck pain
2434 Neck stiffness
1971 Necrosis
1972 Necrosis of flap tissue
1413 Necrosis, pressure
2462 Needle stick/puncture
1974 Neonatal deformities
1975 Neonatal hearing impairment
1976 Neonatal hearing loss
2438 Neoplasm, breast
1978 Neovascularization
1979 Nerve damage
1986 Nerve damage, optical
2362 Nerve palsy, peroneal
1846 Nerve paralysis, facial
1980 Nerve stimulation, undesired
1981 Neural tissue damage
2265 Neurogenic shock
1982 Neurological deficit/dysfunction
1983 Neuropathy
2046 Newborns (RDS), respiratory distress syndrome of
1417 Nicks, cuts or tears of dura or other tissues by device
2162 Nipple sensation, changes in/loss of
2441 Nipple ulceration
2199 No consequences or impact to patient
2093 Nodes, swollen lymph
2250 Nonpyrogenic
2276 Nonresorbable materials, unretrieved in body
2411 Nonspecific
2481 Normal pulmonary arterial wedge pressure
2415 Numbness
2422 Obstruction
1699 Obstruction of airway
2466 Obstruction, nasal
2237 Obstructive pulmonary disease (COPD), chronic
1984 Occlusion
1986 Optical nerve damage
2106 Optical tissue, breakdown of
1987 Organ(s), perforation of
2110 Organ/tissue transplant
1428 Ossification
2377 Osteolysis
2200 Other (for use when an appropriate patient code cannot be identified)
1436 Overcorrection
1988 Overdose
1510 Overdose of radiation
2397 Overinflation of lung
1989 Overmedicated
1990 Oversedated
1991 Overstimulation
2234 Overwear syndrome
2478 Oxygen saturation, high
2477 Oxygen saturation, low
1994 Pain
1776 Pain in chest
2388 Pain relief, inadequate
1685 Pain, abdominal
2355 Pain, joint
2433 Pain, neck
1995 Painful stimulation
2468 Pallor
2467 Palpitations
2362 Palsy, peroneal nerve
1447 Pannus formation
1785 Papillary conjunctivitis, giant

PATIENT-RELATED TERMS (continued)

1997 Paralysis
1846 Paralysis of facial nerve
2448 Paraplegia
1998 Paresis
1707 Patchy, light or insufficient anesthesia
2155 Patient condition, improved
1125 Patient, contraindicated
2199 Patient, no consequences or impact to
2435 Peak expiratory flowrate, decreased
2436 Peak expiratory flowrate, increased
1999 Peeling
2000 Pelvic inflammatory disease, (PID)
2001 Perforation
1792 Perforation of cornea
2399 Perforation of esophagus
1987 Perforation of organ(s)
2277 Perforation of sinus
2121 Perforation of uterus
2135 Perforation of vessel(s)
2152 Perforation, great vessel
2002 Peripheral vascular disease
2003 Peritoneal laceration(s)
2252 Peritonitis
2201 Perivalvular leak(s)
2362 Peroneal nerve palsy
2169 Petit-mal seizures
2367 Pharyngitis
2034 Phenomenon, Raynaud's
2004 Phlebitis
2164 Phosphene visualization
2165 Phototoxicity
2000 PID, pelvic inflammatory disease
1204 Plaque or vessel, device embedded in
2009 Pleomorphism
2010 Pleural effusion
2011 Pneumonia
2012 Pneumothorax
2013 Pocket erosion
1992 Polymyositis
1747 Pooling of blood
2015 Positive antinuclear antibodies (ANA)
2186 Post spinal headache
2446 Post-operative wound infection
2447 Post-traumatic wound infection
2266 Postoperative shock
1819 Pregnancy, ectopic
2465 Premature labor
1936 Pressure (IOP), delayed uncontrolled intraocular
1937 Pressure (IOPR), rise in intraocular
2326 Pressure sores/ulcers
2488 Pressure, high blood
2480 Pressure, high pulmonary arterial wedge
2489 Pressure, low blood
2479 Pressure, low pulmonary arterial wedge
1413 Pressure, necrosis
2481 Pressure, normal pulmonary arterial wedge
2463 Pressure/tightness in chest
1850 Problems, feeding
2102 Problems, thyroid
2042 Procedure repeated, surgical
2357 Procedure, surgical
2475 Prolapse
2471 Prolapse, mitral valve
2177 Prolonged surgery
2480 Pulmonary arterial wedge pressure, high
2479 Pulmonary arterial wedge pressure, low
2481 Pulmonary arterial wedge pressure, normal
2237 Pulmonary disease (COPD), chronic obstructive
2019 Pulmonary dysfunction
2020 Pulmonary edema
1498 Pulmonary embolism
1832 Pulmonary emphysema
2021 Pulmonary infarction
2022 Pulmonary insufficiency
2023 Pulmonary regurgitation
2024 Pulmonary stenosis
2474 Pulmonary valve replacement
2469 Pulse, irregular
2462 Puncture/stick from needle
2025 Punctured blood vessels
2026 Pupillary block
1812 Purulent discharge
2027 Pus
2028 Pyrogenic
2246 Pyrogenic infection
2254 Pyrogenic reaction
2449 Quadriplegia
1755 Radiation burn
1510 Radiation overdose
2256 Radiation sickness syndrome
2166 Radiation underdose
2255 Radiodermatitis
2032 Range of motion, loss of
2033 Rash
2485 Rate of respiration, decreased
2486 Rate of respiration, increased
2034 Raynaud's phenomenon
2046 RDS, respiratory distress syndrome of newborns
2414 Reaction
1297 Reaction of host-tissue
1713 Reaction to antibiotics
1701 Reaction, allergic
1733 Reaction, autoimmune
1868 Reaction, foreign body
2442 Reaction, injection site
2035 Reaction, local
2254 Reaction, pyrogenic
2036 Reaction, systemic
2038 Red eye(s)
2259 Regurgitation
1716 Regurgitation, aortic

PATIENT-RELATED TERMS (continued)

1964 Regurgitation, mitral
2023 Regurgitation, pulmonary
2112 Regurgitation, tricuspid
2335 Regurgitation, valvular
2403 Reinfusion
2392 Reintubate
2365 Removal of foreign body
2039 Renal disease (ESRD), end stage
2041 Renal failure
1985 Reocclusion
2476 Repair, heart valve
2042 Repeated surgical procedure
2472 Replacement of aortic valve
2474 Replacement of pulmonary valve
2473 Replacement of tricuspid valve
2376 Replacement, mitral valve
2482 Respiratory acidosis
2483 Respiratory alkalosis
2044 Respiratory arrest
2045 Respiratory distress
1696 Respiratory distress syndrome of adults (ARDS)
2046 Respiratory distress syndrome of newborns, (RDS)
2484 Respiratory failure
2485 Respiratory rate, decreased
2486 Respiratory rate, increased
2420 Respiratory tract infection, upper
2271 Response, decreased therapeutic
2272 Response, increased therapeutic
1698 Restricted airflow
2400 Resuscitation
2119 Retention, urinary
2048 Retina, damage to
2049 Retina, degeneration of
2047 Retina, detached
2050 Retina, tear(s) in
1957 Retinitis, cytomegaloviral
2051 Retrograde
2052 Retrograde flow
2053 Rheumatic heart disease
1724 Rheumatoid arthritis
1923 Rhythm, idioventricular
2054 Right ventricular dysfunction
2055 Right ventricular failure
2056 Right ventricular hypertrophy
1968 Rigidity, muscular
2103 Ringing in ears
1788 Rise in core temperature
1854 Rise in fetal core temperature
1937 Rise in intraocular pressure, (IOPR)
2208 Rupture
1551 Rupture due to stress from capsular contracture
1901 Rupture of hyaloid face
2058 S. aureus
2478 Saturation, high oxygen
2477 Saturation, low oxygen
1857 Scalp laceration(s), fetal
2358 Scar excision
2060 Scar tissue
1793 Scar, corneal
2061 Scarring
2062 Scleroderma
1718 Score, decreased or low apgar
2368 Sedation
2118 Sedation, not under
2063 Seizures
2261 Seizures, absence
2260 Seizures, focal
2064 Seizures, focal motor
2168 Seizures, grand-mal
2169 Seizures, petit-mal
2146 Sensation, burning
2162 Sensation, changes in/loss of nipple
1869 Sensation, foreign body
2065 Sensitivity
2427 Sensitivity of teeth
2233 Sensitivity, corneal
2066 Sensitization
2067 Sepsis
2068 Septic shock
2069 Seroma
2070 Severed digit(s), (finger or toe)
1803 Shedding of bone debris
2198 Shift, mediastinal
2072 Shock
2108 Shock syndrome (TSS), toxic
1693 Shock, acoustic
1703 Shock, anaphylactic
2262 Shock, cardiogenic
1917 Shock, hypovolemic
2264 Shock, insulin
2265 Shock, neurogenic
2266 Shock, postoperative
2068 Shock, septic
2267 Shock, surgical
2268 Shock, traumatic
2256 Sickness syndrome, radiation
2277 Sinus, perforation of
2073 Sjogren's syndrome
2074 Skin discoloration
2075 Skin erosion
2443 Skin inflammation
2076 Skin irritation
2077 Skull fracture
2251 Sneezing
2396 Sore throat
2079 Soreness
2326 Sores/ulcers, pressure
1966 Spasm(s), muscle
2390 Spinal arachnoiditis
2432 Spinal cord injury
2081 Spinal injury
2082 Spotting

PATIENT-RELATED TERMS (continued)

2083 Sprain
2487 ST segment depression
2059 ST segment elevation
1593 Stacking breaths
2178 Staining
2058 Staphyloccus aureus
2263 Stenosis
1717 Stenosis, aortic
1965 Stenosis, mitral
2024 Stenosis, pulmonary
2113 Stenosis, tricuspid
2462 Stick/puncture from needle
2434 Stiffness, neck
1412 Stimulation of muscle
1980 Stimulation of nerve, undesired
1995 Stimulation, painful
2084 Strangulation
1551 Stress from capsular contracture, rupture due to
2085 Stricture
2086 Stroke
2336 Stroke syndrome
1824 Stromal edema
1893 Subarachnoid hemorrhage
2247 Subclinical infection
1894 Subdural hemorrhage
2087 Subepithelial infiltration
2088 Suffocation
2089 Sunset syndrome
2177 Surgery, prolonged
2357 Surgical procedure
2042 Surgical procedure, repeated
2267 Surgical shock
2444 Sweating
2091 Swelling
2356 Swelling, joint
2092 Swollen glands
2093 Swollen lymph nodes
1610 Syncope
1684 Syndrome (AIDS), acquired immunodeficiency
1696 Syndrome (ARDS), adult respiratory distress
2108 Syndrome (TSS), toxic shock
2046 Syndrome of newborns (RDS), respiratory distress
2239 Syndrome, first use
2234 Syndrome, overwear
2256 Syndrome, radiation sickness
2073 Syndrome, sjogren's
2336 Syndrome, stroke
2089 Syndrome, sunset
2114 Syndrome, twiddler's
2115 Syndrome, uveitis-glaucoma-hyphema (UGH)
2094 Synovitis
2036 Systemic reaction
2095 Tachycardia
1731 Tachycardia, atrial
2132 Tachycardia, ventricular
2226 Tamponade, cardiac
1951 Target points, lesions in
2050 Tear(s) in retina
2235 Tearing, excessive
1417 Tears, nicks or cuts of dura or other tissues by device
2097 Tears, tentorial
2427 Teeth, sensitivity of
1788 Temperature rise, core
1854 Temperature rise, fetal core
2461 Temperature, decreased body
2096 Temperature, elevated body
2097 Tentorial tears
2273 Teratogenic effects
1341 Test, LAL (limulus amebocyte lysate)
2216 Therapeutic abortion
2099 Therapeutic effects, unexpected
2271 Therapeutic response, decreased
2272 Therapeutic response, increased
2396 Throat, sore
2100 Thrombosis
2101 Thrombus
2102 Thyroid problems
2161 Tics, muscular
2463 Tightness/pressure in chest
2171 Tingling
2103 Tinnitus
2104 Tissue damage
1981 Tissue damage, neural
1786 Tissue disease, connective
2105 Tissue failure
1417 Tissue nicks, cuts, or tears by device
2106 Tissue, breakdown of optical
1972 Tissue, necrosis of flap
1297 Tissue, reaction of host
2060 Tissue, scar
2110 Tissue/organ transplant
2070 Toe or finger, severed
2223 Tonic convulsion
2428 Tooth fracture
2107 Torsades-de-Pointes
1794 Touch, corneal
2207 Toxemia
2108 Toxic shock syndrome, (TSS)
2333 Toxicity
2098 Toxins in children
2269 Toxoplasmosis, acquired
2270 Toxoplasmosis, congenital
2393 Tracheostomy
2120 Tract, infection of urinary
2337 Transfusion of blood products
1749 Transfusion with incompatible blood
2109 Transient ischemic attack
2110 Transplant of organ/tissue
1795 Transplant, corneal
1694 Trauma, acoustic
2268 Traumatic shock
2111 Tricuspid insufficiency

PATIENT-RELATED TERMS (continued)

2112 Tricuspid regurgitation
2113 Tricuspid stenosis
2473 Tricuspid valve replacement
2108 TSS, toxic shock syndrome
2114 Twiddler's syndrome
2172 Twitching
2115 UGH (uveitis-glaucoma-hyphema) syndrome
2274 Ulcer
1796 Ulcer, corneal
2116 Ulceration
2441 Ulceration, nipple
2326 Ulcers/sores, pressure
1936 Uncontrolled/delayed intraocular pressure (IOP)
2117 Under no medication
2118 Under no sedation
2166 Underdose, radiation
1980 Undesired nerve stimulation
2099 Unexpected therapeutic effects
2369 Union fracture, delayed
2202 Unknown (for use when the patient's condition is not known)
2490 Unresponsive
1859 Unretrieved fiberoptic fragments in body
2276 Unretrieved nonresorbable materials in body
2420 Upper respiratory tract infection
2188 Uremia
1871 Urgency
2275 Urinary frequency
2119 Urinary retention
2120 Urinary tract infection
2278 Urticaria
2121 Uterine perforation
2122 Uveitis
2115 Uveitis-glaucoma-hyphema (UGH) syndrome
2123 Vaginal discharge
2124 Vaginal mucosa damage
2376 Valve replacement, mitral
2471 Valve, prolapse of mitral
2476 Valve, repair of heart
2472 Valve, replacement of aortic
2474 Valve, replacement of pulmonary
2473 Valve, replacement of tricuspid
1926 Valvular insufficiency
2335 Valvular regurgitation
2002 Vascular disease, peripheral
2126 Vasoconstriction
2127 Vasodilatation
2128 Vasospasm
2071 VD, venereal disease
2071 Venereal disease (VD)
2129 Venipuncture
2395 Ventilator dependent
2078 Ventricle, abnormality of
1947 Ventricular dysfunction, left
2054 Ventricular dysfunction, right
1948 Ventricular failure, left
2055 Ventricular failure, right
2130 Ventricular fibrillation
2131 Ventricular flutter
1949 Ventricular hypertrophy, left
2056 Ventricular hypertrophy, right
2132 Ventricular tachycardia
2133 Ventriculomeglia
2134 Vertigo
1204 Vessel or plaque, device embedded in
2135 Vessels, perforation of
2025 Vessels, punctured blood
2248 Viral infection
2136 Virus
2197 Virus (HIV), human immunodeficiency
2137 Vision, blurring of
2138 Vision, impaired
2139 Vision, loss of
2140 Visual disturbances
2164 Visualization, phosphene
1866 Vitreous floaters
2143 Vitreous fluid, blood in
2142 Vitreous fluid, loss of
2445 Vitreous, detachment of
2181 Vitritis
2430 Volume (FEV), decreased forced expiratory
2431 Volume (FEV), increased forced expiratory
2144 Vomiting
2145 Weakness
1967 Weakness, muscular
2480 Wedge pressure, high pulmonary arterial
2479 Wedge pressure, low pulmonary arterial
2481 Wedge pressure, normal pulmonary arterial
2241 Welt(s)
2241 Wheal(s)
1154 Wound dehiscence
2446 Wound infection, post-operative
2447 Wound infection, post-traumatic

DEVICE-RELATED TERMS

2158 Aberration distortion, lens
1002 Abnormal
2424 Abnormal patch test results
2288 Aborted charge
1387 Abrasion from instrument/object
1003 Absorption
1082 Absorption, carbon
1001 AC/DC power, failure to run on
1004 Accessories, incompatible
1591 Accidental spillage
1512 Accuracy rate
1675 Accuracy, volume
1619 Activate system, failure to
1525 Activated, device remains
1486 Activation of system, premature
1557 Activation/keying, self
1006 Adaptor, failure of
1572 Advise shock, failure to
1007 Agglutinate, failure to
2300 Air eliminator, defective
1008 Air leak(s)
1022 Alarm not visible
1620 Alarm system, failure of check-catheter
1621 Alarm system, failure of gas-leak/loss
1615 Alarm system, failure of message-battery status
1616 Alarm system, failure of message-check electrode
1617 Alarm system, failure of message-leads off
1618 Alarm system, failure of message-service
1010 Alarm, audible
1014 Alarm, defective
1011 Alarm, delayed
1024 Alarm, error of warning
1009 Alarm, failure of arterial pressure
1020 Alarm, failure of fast heart rate
2386 Alarm, failure of high inspiratory pressure
1017 Alarm, failure of low flow
2387 Alarm, failure of low inspiratory pressure
1406 Alarm, failure of monitor display
1025 Alarm, failure of warning
1012 Alarm, failure to
1013 Alarm, false
1015 Alarm, intermittent
1016 Alarm, low audible
1021 Alarm, no lead
1019 Alarm, not audible
2286 Algorithms, inconsistent
1026 Altitude variations
1027 Ambient temperature, changes in
1193 Analysis, failure to perform EKG/ECG
1539 Analyze rhythm, failure to
1622 Angulation of table, unintended
1029 Antenna, failure of
1031 Application problems
2289 Arcing at electrodes
1032 Arcing at paddles
1033 Arm motion, unintended
1009 Arterial pressure alarm, failure of
1036 Artifact
1039 Artificial
1040 Aspherical lens
1041 Aspiration, excessive
1042 Aspiration, incomplete
1050 Asymmetrical balloon
1441 Asynchronous pacing
1010 Audible alarm
1016 Audible alarm, low
1019 Audible alarm, none
1043 Augmentation, loss of
1044 Autofill, unable to
1046 Automatic injection system overinfusion
2307 Automatic injection system underinfusion
1734 Automatic injection system, failure to infuse
1045 Automatic injection system, incompatible
1440 Back-up mode, pacer found in
1047 Back-up, failure to
1048 Back-up, failure to convert to
2303 Bacterial contamination
1050 Balloon asymmetrical
1051 Balloon burst
1052 Balloon leak(s)
1053 Balloon mushroomed
1049 Balloon rupture
1054 Battery charger, defective
1055 Battery failure
1057 Battery, premature discharge of
1355 Bed system, leak(s) from hydraulic
2310 Beds, rips/tears in specialty
1059 Bend
1278 Bent haptic(s)
1060 Bicarbonate
1061 Bifocal lens
1062 Biofilm coating
1063 Blank screen
1064 Bleed back
1065 Blockage
2317 Blood contaminated device
2290 Blood gas measurements, erroneous
1746 Blood in tubing
2318 Blood pooling
1067 Bolus mechanism failure
1068 Bond, failure to
1132 Break of counterbalance
1238 Break(s), filter
1076 Break, cable
1219 Break, external fiberoptic
1257 Break, footrest
1274 Break, handpiece
1277 Break, handrest
1445 Break, pallet
1565 Break, shaft
1625 Break, table
1229 Break/separation, fiberoptic
1073 Breakage of burr

DEVICE-RELATED TERMS (continued)

1069 Breakage of device
1347 Breakage of lead(s)
1638 Breakage of tip
2347 Breakage of wire(s)
1088 Breaker, tripped circuit
1103 Broken component(s)
1279 Broken haptic(s)
2297 Bubble detector, failure of
1070 Bubble(s)
2346 Buckling of tube(s)
2305 Burn hole(s)
1348 Burn(s) from lead(s)
1071 Burned
1073 Burrs, breakage of
1074 Burst
1051 Burst, balloon
1206 Button or switch, failure of emergency stop
1076 Cable break
2302 Cable, defective
1077 Calcification
1189 Calculation error, dose
1449 Calculations of parameter, incorrect
1495 Calculations, incorrect programming of
2440 Calibrate, failure to
1078 Calibration error
1079 Capacitive coupling
1150 Capsulotomy, deflation due to
1547 Capsulotomy, rupture due to
1081 Capture, failure to
1080 Capture, intermittent
1082 Carbon absorption
2319 Cardiac enzyme evaluation, erroneous
1670 Care/use of device, incorrect
1234 Cartridge, unintended ejection of film
1920 Catheter, pull out of IV
1075 Cathode ray tube (CRT) failure
1148 Cause of deflation, unknown
1548 Cause of rupture, unknown
1083 Cautery
1027 Changes in ambient temperature
1084 Channeling
2288 Charge, aborted
1085 Charge, failure to
1054 Charger, defective battery
1086 Charred
1620 Check-catheter alarm system, failure of
1087 Chemical reaction
1088 Circuit breaker tripped
1089 Circuit failure
1231 Cladding material, separation of fiberoptic
1224 Claim, false
1090 Clean, failure to
1213 Cleaner, failure to remove enzymatic
1091 Cleaning, inadequate
1092 Clearance
1093 Cleaver, failure of fiberoptic
1094 Clogged
1359 Cloudy lens
1095 Clumping
1096 Coagulation
1062 Coating, biofilm
2291 Code, failure to override semiautomatic
1097 Coefficient error
1098 Coiled
1099 Collapse
1626 Collapse of table
1188 Collapse, dome
1100 Collimator design problem
1429 Collision, unintended
1101 Colony forming units
1330 Communication, interlumen
1102 Compatibility
2345 Compatibility/incompatibility of electro-magnetic interference
1105 Component(s) falling
1103 Component(s), broken
1104 Component(s), detachment of
1108 Component(s), incompatible
1106 Component(s), overheating of
1107 Component(s), worn
2292 Components, defective
2306 Components, missing
1110 Computer failure
1111 Computer hardware error
1112 Computer software error
1113 Concentrate
1114 Conduct, failure to
1115 Conductivity
1116 Connection error
1371 Connection(s), loose
1117 Connector pin failure
1118 Contact lens, problem with trial set
1200 Contact(s), problem with electrode
1120 Contamination
2317 Contamination of device by blood
1187 Contamination of distilled water
2303 Contamination, bacterial
1121 Continuity, intermittent
1122 Continuous
1123 Continuous firing
1124 Continuous mode failure
1128 Contraindicated coolant
1126 Control settings incorrect
1540 Convert rhythm, failure to
1048 Convert to back-up, failure to
1127 Cool, failure to
1128 Coolant, contraindicated
1129 Cooling system, failure of
1130 Cooling, inadequate
1131 Corrode
1132 Counterbalance break
1571 Counters, resetting of shock
1133 Countershock, failure to deliver
1134 Couple, failure to

DEVICE-RELATED TERMS (continued)

1079 Coupling, capacitive
1135 Crack(s)
1446 Crack(s) in pallet
1639 Crack(s) in tomographic pallet
1549 Crease or fold due to rupture
1136 Cross connection
1137 Cross reactivity
1075 CRT (cathode ray tube) failure
1138 Crush
1139 Cuff degeneration
2454 Cut(s)
1140 Cutoff point
1141 Cutter-torque-cable twisted or tangled
1142 Cycle, failure to
1405 Damage from moisture
1570 Damage from shipping
1151 Damage from surgical instrument, deflation due to
1550 Damage from surgical instrument, rupture due to
2284 Damage, internal/external
1143 Damaged screw tapper
1216 Date of expiration exceeded
1804 Debris, metal shedding
1360 Decentration of lens
1144 Declotting
1145 Decoupling
1500 Decrease of pump speed
1490 Decreased pressure
1146 Decreased suction
2300 Defective air eliminator
1014 Defective alarm
1054 Defective battery charger
2302 Defective cable
2292 Defective components
2294 Defective electrical wires
1147 Defective photomultiplier (PM) tube
2301 Defective seal
1612 Defective syringe
2299 Defective tube(s)
2298 Defective valve(s)
1149 Deflation difficulties
1150 Deflation due to capsulotomy
1151 Deflation due to damage from surgical instrument
1152 Deflation due to trauma
1148 Deflation, cause unknown
1139 Degeneration of cuff
1201 Degeneration of electrode(s)
1153 Degradation
1320 Degradation of insulation
1155 Deionizer, failure of
1011 Delayed alarm
1133 Deliver countershock, failure to
1211 Deliver energy, failure to
1573 Deliver shock, failure to
2338 Deliver, failure to
1508 Delivery of radiation to incorrect body area
2339 Delivery, inaccurate
1157 Deploy, difficult to
1158 Deploy, failure to
1484 Deployment, premature
1232 Deposits on lens
1159 Deprimed
1222 Design failsafe, failure of
1100 Design problem, collimator
1161 Design/structure problem
1280 Detached haptic(s)
1321 Detached insulation
2043 Detachment from respirator
1586 Detachment from source
1104 Detachment of component(s)
1256 Detachment of footrest
1275 Detachment of handpiece
1276 Detachment of handrest
1302 Detachment of parts from IV pole
1576 Detachment of shoulder rest
1577 Detachment of shoulder support
2297 Detector, failure of bubble
2160 Detector, failure of motion
1069 Device breakage
2317 Device contaminated by blood
1162 Device energization, unintended
2379 Device failure
1628 Device material, tears, rips, holes in
1525 Device remains activated
1526 Device remains implanted
1670 Device, incorrect care/use of
1663 Device, inoperable
1328 Device, interference with monitoring
1527 Device, or device fragments remain in patient
1628 Device, tears, rips holes in
1260 Device/material fracture(s)
1541 Diagnose rhythm, failure to
1165 Dialysate
1166 Dialyzer, failure of
1149 Difficult to deflate
1157 Difficult to deploy
1251 Difficult to flush
1254 Difficult to fold
1310 Difficult to inflate
1316 Difficult to insert
1331 Difficult to interrogate
1467 Difficult to position
1487 Difficult to prep
1496 Difficult to program
1528 Difficult to remove
1668 Difficult to unwrap
1680 Difficult to wedge
1168 Disassembly
1352 Disc escape, leaflet
1361 Disc lens
1309 Disc, incomplete opening of
2149 Discharge, electro-static

DEVICE-RELATED TERMS (continued)

1169 Discharge, failure to
1057 Discharge, premature battery
1362 Discoloration of lens
1170 Discolored
1322 Discolored insulation
1171 Disconnect
1629 Discrepancies, telemetry
1376 Discrepancy of magnet mode
1172 Disengaged
1175 Disinfect, failure to
1176 Disinfection, inadequate/improper
1177 Disintegrate
1178 Dislocated
1281 Dislocated haptic(s)
1934 Dislocated intraocular lens (IOL)
1179 Dislodged
1180 Displacement
1181 Display misread
1182 Display, erratic
1183 Display, failure to
1184 Display, incorrect
1304 Displayed image error
1185 Disposable
1607 Disruption of suture line
2412 Dissatisfaction
1186 Dissection
1187 Distilled water, contaminated
2158 Distortion of lens aberration
1188 Dome collapse
1189 Dose calculation error
1191 Drift
1611 Drive problem with syringe
1410 Drive unit, motor stalled or jammed
1192 Dry, failure to
2407 Dull
1414 Dull needle
1234 Ejection of film cartridge, unintended
1193 EKG/ECG analysis, failure to perform
1195 Elective removal
1196 Elective replacement
1483 Elective replacement indicator (ERI), premature
1198 Electrical failure
1197 Electrical shock
2294 Electrical wires, defective
1194 Electro-magnetic interference (EMI)
2345 Electro-magnetic interference (EMI), compatibility/incompatibility
2149 Electro-static discharge
1349 Electrocution from lead(s)
1200 Electrode contact(s), problem with
1201 Electrode(s), degeneration of
1199 Electrode(s), failure of
1202 Electrode(s), fracture of
1203 Electrode(s), migration of
2289 Electrodes, arcing
1205 Emergency power failure
1206 Emergency stop button or switch failure
1207 Emergency table stop failure
2345 EMI, (electro-magnetic interference), compatibility/incompatibility
1194 EMI, electro-magnetic interference
1480 End-of-life (EOL) indicator, premature
1208 Endoscopic accessory fire or melt
1162 Energization of device, unintended
1431 Energy output incorrect
1209 Energy output to patient tissue incorrect
1210 Energy spectrum incorrect
1211 Energy, failure to deliver
1212 Entrapment
1213 Enzymatic cleaner, failure to remove
2319 Enzymes, erroneous evaluation of cardiac
1480 EOL (end-of-life) indicator, premature
1483 ERI (elective replacement indicator), premature
1214 Erosion
1182 Erratic display
2290 Erroneous blood gas measurements
2319 Erroneous cardiac enzyme evaluation
1345 Error of laser pulse timing
1024 Error of warning alarm
1215 Error or warning message, failure to produce
1078 Error, calibration
1097 Error, coefficient
1111 Error, computer hardware
1112 Error, computer software
1116 Error, connection
1189 Error, dose calculation
1304 Error, image display
1317 Error, installation
2319 Evaluation of cardiac enzymes, erroneous
1216 Exceeded expiration date
1567 Exceeded shelf life
1041 Excessive aspiration
1464 Exchange of gas, poor
1216 Expiration date exceeded
1603 Expiratory or inspiratory phase, stuck in
1485 Explantation, premature
1217 Explanted
1218 Explode
1651 Exploding tube(s)
1301 Explosion during hydrogen peroxide sterilization
1509 Exposure to radiation, unintended
1219 External fiberoptic break
2284 External/internal damage
1220 Extra needle
1221 Extraneous radiofrequency wave transmission
2154 Extrusion of implant
1222 Failsafe design failure
1006 Failure of adaptor
1029 Failure of antenna
1009 Failure of arterial pressure alarm
1734 Failure of automatic injection system to infuse
1055 Failure of battery

DEVICE-RELATED TERMS (continued)

1067 Failure of bolus mechanism
2297 Failure of bubble detector
1075 Failure of cathode ray tube (CRT)
1620 Failure of check-catheter alarm system
1089 Failure of circuit
1117 Failure of connector pin
1129 Failure of cooling system
1155 Failure of deionizer
2379 Failure of device
1166 Failure of dialyzer
1199 Failure of electrode(s)
1205 Failure of emergency power
1206 Failure of emergency stop button or switch
1207 Failure of emergency table stop
1222 Failure of failsafe design
1020 Failure of fast heart rate alarm
1093 Failure of fiberoptic cleaver
2151 Failure of film processor
1258 Failure of footswitch
1263 Failure of function indicator light(s)
1265 Failure of gas delivery system
1621 Failure of gas-leak/loss alarm system
1283 Failure of head immobilizer
2386 Failure of high inspiratory pressure alarm
1300 Failure of hydraulic system
2157 Failure of interlock(s)
1367 Failure of lens washers
1369 Failure of lockout mechanism
1017 Failure of low flow alarm
2387 Failure of low inspiratory pressure alarm
1375 Failure of magnet
1615 Failure of message-battery status alarm system
1616 Failure of message-check electrode alarm system
1617 Failure of message-leads off alarm system
1618 Failure of message-service alarm system
2382 Failure of meter
1407 Failure of monitor
1406 Failure of monitor display alarm
2160 Failure of motion detector
1409 Failure of motor
1489 Failure of pressure sensor
1493 Failure of probe
1513 Failure of rate modulated pacing sensor
1519 Failure of receiver
1520 Failure of receiver stimulator unit
1568 Failure of shielding
1578 Failure of shunts
1579 Failure of shutter
1580 Failure of side rails
2324 Failure of solder joint
1590 Failure of speech processor
2304 Failure of stopcock valve
2323 Failure of surgical graft
1619 Failure of system to activate
1632 Failure of threader
1635 Failure of timer
1646 Failure of transducer
1647 Failure of transmitter
1648 Failure of trocar
1672 Failure of valve(s)
1025 Failure of warning alarm
2315 Failure of water purification system
1677 Failure of water softener process
1572 Failure to advise shock
1007 Failure to agglutinate
1012 Failure to alarm
1539 Failure to analyze rhythm
1047 Failure to back-up
1068 Failure to bond
2440 Failure to calibrate
1081 Failure to capture
1085 Failure to charge
1090 Failure to clean
1114 Failure to conduct
1540 Failure to convert rhythm
1048 Failure to convert to back-up
1127 Failure to cool
1134 Failure to couple
1142 Failure to cycle
2338 Failure to deliver
1133 Failure to deliver countershock
1211 Failure to deliver energy
1573 Failure to deliver shock
1158 Failure to deploy
1541 Failure to diagnose rhythm
1169 Failure to discharge
1175 Failure to disinfect
1183 Failure to display
1192 Failure to dry
1252 Failure to flush
1255 Failure to fold
1286 Failure to heat
2340 Failure to infuse
1332 Failure to interrogate
1379 Failure to maintain
1863 Failure to osseointegrate
1542 Failure to override rhythm
2291 Failure to override semiautomatic code
1439 Failure to pace
1193 Failure to perform EKG/ECG analysis
1476 Failure to power-up
1488 Failure to prep
1492 Failure to prime
1215 Failure to produce error or warning message
1497 Failure to program
1502 Failure to pump
1581 Failure to read input signal
1517 Failure to recalibrate
1213 Failure to remove enzymatic cleaner
1532 Failure to reset
1536 Failure to retract
1001 Failure to run on AC/DC power
1466 Failure to run on portable mode

DEVICE-RELATED TERMS (continued)

1582 Failure to select signal
1563 Failure to service
2170 Failure to suction
1521 Failure to transmit record
1669 Failure to unwrap
1683 Failure to zero
1110 Failure, computer
1124 Failure, continuous mode
1198 Failure, electrical
1299 Failure, hybrid
1323 Failure, insulation
1223 Failure, intermittent
1384 Failure, mechanical
1312 Failure, no infusion of injector system
2311 Failure, out-of-box
1313 Failure, overinfusion of injector system
1314 Failure, underinfusion of injector system
1105 Falling component(s)
1013 False alarm
1224 False claim
1226 False output
1228 False readings
1225 False-negative test result
1227 False-positive test result
1020 Fast heart rate alarm, failure of
1649 Fiber/trocar incompatibility
1230 Fiberguide incompatibility
1334 Fiberoptic break or fragmentation during intra-cavity procedure
1219 Fiberoptic break, external
1229 Fiberoptic break/separation
1231 Fiberoptic cladding material separation
1093 Fiberoptic cleaver, failure of
1233 Filling problem
1234 Film cartridge ejection, unintended
1235 Film processing, inadequate
2151 Film processor failure
1236 Filter
1238 Filter break(s)
1237 Filter leak(s)
1242 Filter tear(s)
1243 Filter, assembly
1244 Filter, inadequate
1679 Filter, problem with wedge
1556 Filter, problems with sediment
2308 Filtration process, inadequate
1245 Fire
1335 Fire or flash during intraprocedure
1208 Fire or melting of endoscopic accessories
1123 Firing, continuous
2183 Fitting problems
2383 Fixation, revision of internal
1246 Flaking
1247 Flammable
1335 Flash or fire during intraprocedure
1249 Flowrate, inaccurate
1248 Flowrate, restricted
1634 Fluctuations of tidal volume
1250 Fluid leak(s)
1251 Flush, difficult to
1252 Flush, failure to
1290 Flux rate, high
1253 Fogging
1549 Fold or crease due to rupture
1254 Fold, difficult to
1255 Fold, failure to
1257 Footrest break
1256 Footrest detachment
1258 Footswitch failure
1259 Foreign material
1202 Fracture of electrode(s)
1282 Fracture of haptic(s)
1350 Fracture of lead(s)
2413 Fracture of leaflet
1260 Fracture(s) of device/material
1602 Fracture, strut
1261 Fragmentation
1334 Fragmentation or fiberoptic break during intra-cavity procedure
1527 Fragments of device remain in patient
1262 Frayed
1263 Function indicator light(s), failure of
2316 Fungus
1264 Gain, inadequate
1265 Gas delivery system failure
1464 Gas exchange, poor
1621 Gas leak/loss alarm system, failure of
1266 Gas output, improper
1267 Gel leakage
1268 Germicide
1269 Glass, shattered
1270 Gradient increase
2323 Graft, failure of surgical
1271 Grounding malfunctions
1272 Growth, will not support
1274 Handpiece break
1275 Handpiece detachment
1277 Handrest break
1276 Handrest detachment
1278 Haptic(s), bent
1279 Haptic(s), broken
1280 Haptic(s), detached
1281 Haptic(s), dislocated
1282 Haptic(s), fractured
1111 Hardware error, computer
1283 Head immobilizer failure
1284 Head motion, unintended
1681 Head(s) on screw, incorrect
1285 Heat
1286 Heat, failure to
1287 Heating, inadequate
1289 Hemofiltration
1290 High flux rate
1291 High impedance

DEVICE-RELATED TERMS (continued)

2386 High inspiratory pressure alarm, failure of
1433 High output
2426 High pH
1470 High potentiometer readings
1491 High pressure
2459 High readings
2457 High test results
1293 Hole(s)
1325 Hole(s) in insulation
1613 Hole(s) in syringe
2305 Hole(s), burn
1628 Holes, rips, tears in device, device material
2385 Holes, rips, tears in packaging
1553 Homemade saline, use of
1294 Hose line occlusion
1295 Hose line rupture
1296 Hose mismatch
1298 Hot oil leak
1299 Hybrid failure
1355 Hydraulic bed system, leak(s) from
1300 Hydraulic system failure
1301 Hydrogen peroxide sterilization, explosion during
1303 Ignited
1304 Image display error
1408 Image on monitor of poor quality
1305 Image orientation incorrect
1306 Image resolution poor
1358 Image reversal, left or right
1291 Impedance, high
2285 Impedance, low
2154 Implant extrusion
2384 Implant, lens
2320 Implant, removal of
2321 Implant, repositioning of
2322 Implant, reprogramming of
1526 Implanted, device remains
1307 Imprecision
1266 Improper gas output
2309 Improper rinsing
1176 Improper/inadequate disinfection
1393 Improper/incorrect method
2017 Improper/incorrect procedure
1337 Inability to irrigate
2339 Inaccurate delivery
1249 Inaccurate flowrate
1614 Inaccurate markings on syringe
1005 Inaccurate measurements
1609 Inaccurate synchronization
2456 Inaccurate test results
1662 Inactivation of unit
1091 Inadequate cleaning
1130 Inadequate cooling
1235 Inadequate film processing
1244 Inadequate filter
2308 Inadequate filtration process
1264 Inadequate gain
1287 Inadequate heating
1318 Inadequate instructions
1442 Inadequate pacing
1533 Inadequate resistance
2167 Inadequate safety interlock(s)
1564 Inadequate service
1569 Inadequate shielding
1596 Inadequate sterilization
1600 Inadequate storage
1643 Inadequate training
1176 Inadequate/improper disinfection
2280 Inappropriate prompts
1574 Inappropriate shock
2283 Inaudible voice prompts
2345 Incompatibility/compatibility of electro-magnetic interference (EMI)
1004 Incompatible accessories
1045 Incompatible automatic injection system
1108 Incompatible component(s)
1230 Incompatible fiberguide
1630 Incompatible test strips
1649 Incompatible trocar/fiber
1650 Incompatible trocar/instrument
1042 Incomplete aspiration
1309 Incomplete opening of disc
2312 Incomplete/missing packaging
2286 Inconsistent algorithms
1126 Incorrect control settings
1508 Incorrect delivery of radiation to a body area
1184 Incorrect display
1431 Incorrect energy output
1209 Incorrect energy output to patient tissue
1210 Incorrect energy spectrum
1305 Incorrect image orientation
1319 Incorrect instructions
1383 Incorrect measurements
1424 Incorrect occlusion
1449 Incorrect parameter calculations
1654 Incorrect placement of tubing
1494 Incorrect product
1495 Incorrect programming of calculations
1535 Incorrect results
1543 Incorrect rhythm interpretation
1681 Incorrect screw head(s)
1555 Incorrect seal
1583 Incorrect size
1588 Incorrect source
1623 Incorrect table incrementation
1670 Incorrect use/care of device
1676 Incorrect warning light
1682 Incorrect wavelength
1393 Incorrect/improper method
2017 Incorrect/improper procedure
2405 Incorrectly placed syringe markings
1374 Increase milliamps (MA), unable to
1270 Increase of gradient
1501 Increase of pump speed

DEVICE-RELATED TERMS (continued)

1491 Increased pressure
1604 Increased suction
1623 Incrementation of table incorrect
1263 Indicator of function light(s), failure of
1310 Inflation difficulties
1734 Infuse, failure of automatic injection system to
1312 Infuse, failure of injection system to
2340 Infuse, failure to
2341 Infusion, intermittent
1734 Injection system (automatic), failure to infuse
1045 Injection system (automatic), incompatible
1046 Injection system (automatic), overinfusion of
2307 Injection system (automatic), underinfusion of
1312 Injector system failure, no infusion
1313 Injector system failure, overinfusion of
1314 Injector system failure, underinfusion of
1663 Inoperable device
1581 Input signal, failure to read
1316 Insertion difficulties
1603 Inspiratory or expiratory phase, stuck in
2386 Inspiratory pressure alarm, failure of high
2387 Inspiratory pressure alarm, failure of low
1317 Installation error
1318 Instructions, inadequate
1319 Instructions, incorrect
1387 Instrument/object, abrasion from
1650 Instrument/trocar incompatibility
2391 Insufficient pressure
1320 Insulation degradation
1323 Insulation failure
1321 Insulation, detached
1322 Insulation, discolored
1325 Insulation, hole(s) in
1326 Insulation, none
1327 Interference
2345 Interference (EMI), compatibility, incompatibility of electro-magnetic
1194 Interference (EMI), electro-magnetic
2314 Interference (RFI), radiofrequency
1328 Interference with monitoring device
1329 Interference with pacemaker
1378 Interference, magnetic
2157 Interlock(s), failure of
2167 Interlock(s), inadequate safety
1330 Interlumen communication
1015 Intermittent alarm
1080 Intermittent capture
1121 Intermittent continuity
1223 Intermittent failure
2341 Intermittent infusion
1443 Intermittent pacing
1558 Intermittent sensing
2287 Intermittent shock
1599 Intermittently stops
2383 Internal fixation, revision of
2284 Internal/external damage
1543 Interpretation of rhythm, incorrect
1331 Interrogate, difficult to
1332 Interrogate, failure to
1334 Intra-cavity procedure, fiberoptic break or fragmentation during
1335 Intraprocedure, fire or flash during
1919 Intrauterine contraceptive device (IUD), removal of
1336 Invagination
2293 Invalid sensing
1934 IOL (intraocular lens), dislocated
1935 IOL (intraocular lens), migration of
1337 Irrigate, inability to
1919 IUD (intrauterine contraceptive device), removal of
1920 IV catheter pull out
1302 IV pole, detachment of parts from
1410 Jammed or stalled motor drive unit (MDU)
1557 Keying/activation, self
1338 Kinetic
1339 Kink
1340 Knot
2381 Laparoscopic sterilization
1342 Laser nozzle separation
1343 Laser output above specifications
1344 Laser output, unintended
1345 Laser pulse timing error
1346 Laser tip separation
1021 Lead alarm, none
1347 Lead(s), breakage of
1348 Lead(s), burn(s) from
1349 Lead(s), electrocution from
1350 Lead(s), fracture of
1351 Lead(s), shock from
1352 Leaflet disc escape
2413 Leaflet fracture
1298 Leak of hot oil
1354 Leak(s)
1355 Leak(s) from hydraulic bed system
1587 Leak(s) from source
1008 Leak(s), air
1052 Leak(s), balloon
1237 Leak(s), filter
1250 Leak(s), fluid
1390 Leak(s), membrane
1450 Leak(s), paravalvular
1457 Leak(s), perivalvular
1465 Leak(s), port
1357 Leak, radiation
1267 Leakage of gel
1358 Left or right image reversal
1934 Lens (IOL), dislocated intraocular
1935 Lens (IOL), migration of intraocular
2158 Lens aberration, distortion of
2384 Lens implant
2184 Lens replacement
1367 Lens washers, failure of
1040 Lens, aspherical

DEVICE-RELATED TERMS (continued)

1061 Lens, bifocal
1359 Lens, cloudy
1360 Lens, decentration of
1232 Lens, deposits on
1361 Lens, disc
1362 Lens, discoloration of
1363 Lens, malposition of
1411 Lens, multifocal
1364 Lens, opacification of
1118 Lens, problems with trial set of contact
1365 Lens, repositioning of
1640 Lens, toric
1366 Lens, vaulting
1263 Light(s), failure of function indicator
1676 Light, incorrect warning
1294 Line, occlusion of hose
1295 Line, rupture of hose
1368 Linear
1369 Lockout mechanism failure
1370 Looping
1372 Loose
1371 Loose connection(s)
2296 Loose temperature probe
1043 Loss of augmentation
2408 Loss of osseointegration
1475 Loss of power
1534 Loss of resistance
1633 Loss of threshold
1671 Loss of vacuum
1016 Low audible alarm
1017 Low flow alarm, failure of
2285 Low impedance
2387 Low inspiratory pressure alarm, failure of
1434 Low output
2425 Low pH
1471 Low potentiometer readings
1490 Low pressure
2460 Low readings
2458 Low test results
1373 Lubrication
1374 MA (milliamps), unable to increase
1375 Magnet failure
1376 Magnet mode discrepancy
1377 Magnet quench, unintended
1378 Magnetic interference
1379 Maintain, failure to
2409 Malfunction
1271 Malfunction of grounding
1637 Malfunction of timer
1363 Malposition of lens
1614 Markings on syringe, inaccurate
2405 Markings on syringe, incorrectly placed
1381 Markings unclear
1382 Markings, none
1259 Material, foreign
1260 Material/device fracture(s)
1410 MDU (motor drive unit), stalled or jammed
2290 Measurements, erroneous blood gas
1005 Measurements, inaccurate
1383 Measurements, incorrect
1384 Mechanical failure
1067 Mechanism, failure of bolus
1369 Mechanism, failure of lockout
1208 Melting or fire of endoscopic accessories
1385 Melts
1390 Membrane leak(s)
1391 Membrane tear(s)
1215 Message, failure to produce error or warning
1615 Message-battery status alarm system, failure of
1616 Message-check electrode alarm system, failure of
1617 Message-leads off alarm system, failure of
1618 Message-service alarm system, failure of
1804 Metal shedding debris
1392 Meter
2382 Meter failure
1393 Method, improper/incorrect
1395 Migration
1203 Migration of electrode(s)
1935 Migration of intraocular lens (IOL)
1374 Milliamps (MA) rate, unable to increase
1396 Mineralization
1397 Misapplication
1398 Misassembly
1473 Miscalculation of power
2410 Miscalibration
1399 Misconnection
1401 Misfocusing
1402 Mislabeled
1403 Mislocation
1296 Mismatched hose
1404 Misplacement
1181 Misreading of display
2306 Missing components
2312 Missing/incomplete packaging
2295 Mistiming of water softener regeneration cycle
1124 Mode failure, continuous
1466 Mode, failure to run on portable
1440 Mode, pacer found in back-up
1405 Moisture damage
1406 Monitor display alarm, failure of
1407 Monitor failure
1408 Monitor, image quality poor
1328 Monitoring device, interference with
2160 Motion detector failure
1430 Motion of system, unintended
1624 Motion of table top, unintended
1033 Motion, unintended arm
1410 Motor drive unit (MDU) stalled or jammed
1409 Motor failure
1411 Multifocal lens
1053 Mushroomed balloon
1414 Needle, dull
1220 Needle, extra

DEVICE-RELATED TERMS (continued)

1415 Needle, separation
1416 Needle, unsheathed
1019 No audible alarm
1326 No insulation
1021 No lead alarm
1382 No markings
1435 No output
1559 No sensing
1022 No visible alarm
2282 No voice prompts
2163 Noise
1418 Non-linear
1419 Nonpyrogenic
1420 Nonstandard
1421 Nonsterility
1422 Normal
1342 Nozzle separation from laser
2423 Obstruction
1516 Obtain readings, unable to
1423 Occlusion
1294 Occlusion of hose line
1424 Occlusion, incorrect
1425 Odor
1298 Oil leak, hot
1364 Opacification of lens
1426 Opaque
1309 Opening of disc incomplete
1305 Orientation of image incorrect
1538 Osmosis, reversed
1863 Osseointegrate, failure to
2408 Osseointegration, loss of
2203 Other (for use when an appropriate device code cannot be identified)
2311 Out-of-box failure
1432 Output above specifications
1431 Output energy incorrect
1343 Output from laser above specifications
1344 Output from laser, unintended
1209 Output of energy to patient tissue incorrect
1266 Output of gas, improper
1226 Output, false
1433 Output, high
1434 Output, low
1435 Output, none
2342 Overdelivery
2313 Overexposure, radiation
2404 Overfill
1437 Overheat
1106 Overheating of component(s)
1644 Overheating of transducer
1645 Overheating of transducer probe
1311 Overinfusion
1046 Overinfusion of automatic injection system
1313 Overinfusion of injector system
1542 Override rhythm, failure to
2291 Override semiautomatic code, failure to
1438 Oversensing
1439 Pace, failure to
1329 Pacemaker, interference with
1440 Pacer found in back-up mode
1441 Pacing asynchronously
1442 Pacing inadequately
1443 Pacing intermittently
1513 Pacing sensor, failure of rate modulated
2312 Packaging, incomplete/missing
2385 Packaging, tears, rips, holes in
1444 Packaging, unsealed
1032 Paddles, arcing at
1445 Pallet break
1446 Pallet crack(s)
1639 Pallet crack(s), tomographic
1448 Paramagnetic
1449 Parameter calculations, incorrect
1450 Paravalvular leak(s)
1451 Particulates
2424 Patch test, abnormal results of
1527 Patient, device or device fragments remain in
1454 Peeling
1455 Percutaneous
2205 Perforation
1456 Performance
1457 Perivalvular leak(s)
1301 Peroxide sterilization, explosion during hydrogen
2426 pH, high
2425 pH, low
1458 Phantom problem
1507 Phenomenon, R on T
1147 Photomultiplier (PM) tube, defective
1459 Pierce
1117 Pin connector, failure of
1460 Pitting
1654 Placement of tubing, incorrect
1461 Plugged
1462 Plunge
1147 PM (photomultiplier) tube, defective
1463 Pocket stimulation
1302 Pole, detachment of parts from IV
2318 Pooling of blood
1464 Poor gas exchange
1306 Poor image resolution
1506 Poor or unsatisfactory quality
1408 Poor quality of monitor image
1465 Port leak(s)
1466 Portable mode, failure to run on
1467 Positioning difficulties
1469 Potency
1470 Potentiometer readings, high
1471 Potentiometer readings, low
1474 Power surge
1205 Power, failure of emergency
1001 Power, failure to run on AC/DC
1475 Power, loss of
1473 Power, miscalculation of

DEVICE-RELATED TERMS (continued)

1476 Power-up, failure to
1477 Pre/post-pumping problems
1478 Precipitate
1479 Precision
1484 Premature deployment
1057 Premature discharge of battery
1480 Premature end-of-life (EOL) indicator
1483 Premature ERI (elective replacement indicator)
1485 Premature explantation
1486 Premature system activation
1487 Prep, difficult to
1488 Prep, failure to
1009 Pressure alarm, failure of arterial
2386 Pressure alarm, failure of high inspiratory
2387 Pressure alarm, failure of low inspiratory
1489 Pressure sensor failure
1490 Pressure, decreased
1491 Pressure, high
1491 Pressure, increased
2391 Pressure, insufficient
1490 Pressure, low
1492 Prime, failure to
1493 Probe failure
1645 Probe overheating, transducer
2296 Probe, loose temperature
1100 Problem with collimator design
1118 Problem with contact lens trial set
1161 Problem with design/structure
1200 Problem with electrode contact(s)
1511 Problem with radio signals
1561 Problem with sensor(s)
1570 Problem with shipping
1592 Problem with spring loading mechanism
1594 Problem with steering wire
1611 Problem with syringe drive
1679 Problem with wedge filter
1233 Problem, filling
1458 Problem, phantom
1477 Problems with pre/post pumping
1556 Problems with sediment filter
1031 Problems, application
2183 Problems, fitting
2017 Procedure, improper/incorrect
1677 Process, failure of water softener
1235 Processing of film, inadequate
2151 Processor, failure of film
1494 Product, incorrect
1496 Program, difficult to
1497 Program, failure to
1495 Programming calculations, incorrect
2281 Prompts will not clear
2280 Prompts, inappropriate
2283 Prompts, inaudible voice
2282 Prompts, no voice
1920 Pull out of IV catheter
1500 Pump speed, decreased
1501 Pump speed, increased
1502 Pump, failure to
1477 Pumping problems, pre/post
1503 Pumping, stopped
1504 Puncture
1505 Pyrogenic
1408 Quality of monitor image, poor
1506 Quality, unsatisfactory or poor
1377 Quench of magnet, unintended
1507 R on T phenomenon
1508 Radiation delivered to incorrect body area
1509 Radiation exposure, unintended
1357 Radiation leak
2313 Radiation overexposure
2031 Radiation underexposure
1511 Radio signal problems
2314 Radiofrequency interference (RFI)
1221 Radiofrequency wave transmission, extraneous
1580 Rails, failure of side
1513 Rate modulated pacing sensor, failure of
1512 Rate, accuracy
1514 Reaction
1087 Reaction, chemical
1137 Reactivity, cross
1581 Read input signal, failure to
1470 Readings on potentiometer, high
1471 Readings on potentiometer, low
1228 Readings, false
2459 Readings, high
2460 Readings, low
1516 Readings, unable to obtain
1517 Recalibrate, failure to
1518 Recannulation
1519 Receiver failure
1520 Receiver stimulator unit, failure of
1521 Record, failure to transmit
1522 Reflux
1523 Regenerate
2295 Regeneration cycle, mistiming of water softener
1524 Rejection
1527 Remains in patient, device or device fragments
1528 Removal difficulties
2320 Removal of implant
1919 Removal of intrauterine contraceptive device (IUD)
1195 Removal, elective
1213 Remove enzymatic cleaner, failure to
1529 Repair
1530 Replace
2184 Replacement of lens
1196 Replacement, elective
2321 Repositioning of implant
1365 Repositioning of lens
2322 Reprogramming of implant
1531 Reservoir
1532 Reset, failure to
1571 Resetting of shock counters

DEVICE-RELATED TERMS (continued)

2325 Residue
1533 Resistance, inadequate
1534 Resistance, loss of
1306 Resolution, poor image
2043 Respirator, detachment from
1248 Restricted flowrate
1225 Result, false-negative test
1227 Result, false-positive test
1535 Results incorrect
2424 Results of patch test, abnormal
2457 Results of tests, high
2456 Results of tests, inaccurate
2458 Results of tests, low
1631 Results, unexpected therapeutic
1536 Retract, failure to
1537 Reuse
1358 Reversal of image, left or right
1538 Reverse osmosis
2383 Revision of internal fixation
2314 RFI, radiofrequency interference
1539 Rhythm, failure to analyze
1540 Rhythm, failure to convert
1541 Rhythm, failure to diagnose
1542 Rhythm, failure to override
1543 Rhythm, incorrect interpretation of
1358 Right or left image reversal
1544 Rigid
2309 Rinsing, improper
1628 Rips, tears, holes in device, device material
2385 Rips, tears, holes in packaging
2310 Rips/tears in specialty beds
1545 Runaway
1546 Rupture
1547 Rupture due to capsulotomy
1550 Rupture due to damage from surgical instrument
1552 Rupture due to trauma
1049 Rupture of balloon
1295 Rupture of hose line
1548 Rupture, cause unknown
1549 Rupture, fold or crease due to
2167 Safety interlock(s) inadequate
1553 Saline, use of homemade
1554 Salt tablet(s), use of
1063 Screen, blank
1681 Screw head(s) incorrect
1143 Screw tapper, damaged
2301 Seal, defective
1555 Seal, incorrect
1556 Sediment filter problems
1582 Select signal, failure to
1557 Self-activation/keying
2291 Semiautomatic code, failure to override
1558 Sensing intermittently
2293 Sensing, invalid
1559 Sensing, none
1560 Sensitivity
1561 Sensor problems
1489 Sensor, failure of pressure
1513 Sensor, failure of rate modulated pacing
1562 Separates
1342 Separation from laser nozzle
1346 Separation from laser tip
1231 Separation of fiberoptic cladding material
1415 Separation of needle
1608 Separation of suture line
1229 Separation/break, fiberoptic
1563 Service, failure to
1564 Service, inadequate
1118 Set, problems with trial contact lens
1126 Setting of controls, incorrect
1565 Shaft break
1566 Shaft, split
1269 Shattered glass
1652 Shattered tube(s)
1804 Shedding of metal debris
1567 Shelf life exceeded
1568 Shielding failure
1569 Shielding, inadequate
1570 Shipping damage or problem
1571 Shock counters, resetting of
1351 Shock from lead(s)
1197 Shock, electrical
1572 Shock, failure to advise
1573 Shock, failure to deliver
1574 Shock, inappropriate
2287 Shock, intermittent
1575 Short fill
1576 Shoulder rest, detachment of
1577 Shoulder support, detachment of
1578 Shunts, failure of
1579 Shutter failure
1580 Side rails, failure of
1511 Signal problems, radio
1581 Signal, failure to read input
1582 Signal, failure to select
1583 Size, incorrect
1584 Slippage
1585 Smoke
1112 Software error, computer
2324 Solder joint failure
1586 Source, detachment from
1588 Source, incorrect
1587 Source, leak(s) from
1665 Source, unretracted
2310 Specialty beds, rips/tears in
1343 Specifications, laser output above
1432 Specifications, output above
1589 Specificity
1210 Spectrum, incorrect energy
1590 Speech processor failure
1500 Speed of pump, decreased
1501 Speed of pump, increased
1591 Spillage, accidental

DEVICE-RELATED TERMS (continued)

1566 Split, shaft
1653 Splitting of tube(s)
1592 Spring loading mechanism problem
1410 Stalled or jammed motor drive unit (MDU)
2149 Static discharge, electro-
1594 Steering wire problem
1595 Sterility
2381 Sterilization of laparoscope
1301 Sterilization using hydrogen peroxide, explosion during
1596 Sterilization, inadequate
1597 Sticking
1673 Sticking valve(s)
1463 Stimulation, pocket
1520 Stimulator receiver unit, failure of
1206 Stop button or switch, failure of emergency
2304 Stopcock valve, failure of
1503 Stopped pumping
1599 Stops intermittently
1600 Storage, inadequate
1601 Stretched
1630 Strips used for testing, incompatible
1161 Structure/design problem
1602 Strut fracture
1603 Stuck in inspiratory or expiratory phase
2170 Suction failure
1146 Suction, decreased
1604 Suction, increased
1605 Superheat
1606 Supplier
1474 Surge of power
2323 Surgical graft, failure of
1151 Surgical instrument, deflation due to damage from
1550 Surgical instrument, rupture damage due to
1607 Suture line disruption
1608 Suture line separation
1206 Switch or button stop, failure of emergency
1609 Synchronization, inaccurate
1611 Syringe drive problem
1614 Syringe markings inaccurate
2405 Syringe markings, incorrectly placed
1612 Syringe, defective
1613 Syringe, hole(s) in
1619 System fails to activate
1620 System failure of check-catheter alarm
1621 System failure of gas-leak/loss alarm
1615 System failure of message-battery status alarm
1616 System failure of message-check electrode alarm
1617 System failure of message-leads off alarm
1618 System failure of message-service alarm
1430 System motion, unintended
1129 System, failure of cooling
1265 System, failure of gas delivery
1300 System, failure of hydraulic
2315 System, failure of water purification
1486 System, premature activation of
2307 System, underinfusion of automatic injection
1622 Table angulation, unintended
1625 Table break
1626 Table collapse
1623 Table incrementation incorrect
1207 Table stop, failure of emergency
1624 Table top motion, unintended
1554 Tablet(s), use of salt
1141 Tangled or twisted cutter-torque-cable
1627 Tap water, use of
1242 Tear(s), filter
1391 Tear(s), membrane
1628 Tears, rips, holes in device, device material
2385 Tears, rips, holes in packaging
2310 Tears/rips in specialty beds
1629 Telemetry discrepancies
2296 Temperature probe, loose
1027 Temperature, changes in ambient
1225 Test result, false-negative
1227 Test result, false-positive
2424 Test results, abnormal patch
2457 Test results, high
2456 Test results, inaccurate
2458 Test results, low
1630 Test strips, incompatible
1631 Therapeutic results, unexpected
1632 Threader failure
1633 Threshold, loss of
1634 Tidal volume fluctuations
1635 Timer failure
1637 Timer malfunction
1345 Timing error, laser pulse
1638 Tip breakage
1346 Tip of laser, separation from
1209 Tissue, incorrect energy output to patient's
1639 Tomographic pallet crack(s)
1640 Toric lens
1641 Torqued
1642 Tracking
1643 Training, inadequate
1646 Transducer failure
1644 Transducer overheating
1645 Transducer probe overheating
1221 Transmission, extraneous radiofrequency wave
1521 Transmit record, failure to
1647 Transmitter failure
1152 Trauma, deflation due to
1552 Trauma, rupture due to
1678 Treatment, water
1118 Trial contact lens set, problems with
1088 Tripped circuit breaker
1648 Trocar failure
1649 Trocar/fiber incompatibility
1650 Trocar/instrument incompatibility
2346 Tube(s), buckling of
2299 Tube(s), defective

DEVICE-RELATED TERMS (continued)

1651 Tube(s), exploding of
1652 Tube(s), shattering of
1653 Tube(s), splitting of
1746 Tubing, blood in
1654 Tubing, incorrect placement of
1141 Twisted or tangled cutter-torque-cable
1655 Twisting
1656 Ultrafiltration
1657 Ultraviolet
1658 Ultraviolet absorbing
1044 Unable to autofill
1374 Unable to increase milliamps (MA)
1516 Unable to obtain readings
1381 Unclear markings
1659 Uncoiled
1660 Undercorrection
2343 Underdelivery
2031 Underexposure, radiation
2182 Underinfusion
2307 Underinfusion of automatic injection system
1314 Underinfusion of injector system
1661 Undersensing
1631 Unexpected therapeutic results
1033 Unintended arm motion
1429 Unintended collision
1162 Unintended device energization
1234 Unintended film cartridge ejection
1284 Unintended head motion
1344 Unintended laser output
1377 Unintended magnet quench
1509 Unintended radiation exposure
1430 Unintended system motion
1622 Unintended table angulation
1624 Unintended table top motion
1662 Unit inactivated
1520 Unit, failure of receiver stimulator
1101 Units, colony forming
2204 Unknown (for use when the device problem is not known)
1148 Unknown cause of deflation
1548 Unknown cause of rupture
1664 Unravel
1665 Unretracted source
1506 Unsatisfactory or poor quality
1444 Unsealed packaging
1416 Unsheathed needle
1667 Unstable
1668 Unwrap, difficult to
1669 Unwrap, failure to
1627 Use of tap water
1670 Use/care of device, incorrect
1671 Vacuum, loss of
2298 Valve(s), defective
1672 Valve(s), failure of
1673 Valve(s), sticking
2304 Valve, failure of stopcock
1026 Variations in altitude
1366 Vaulting of lens
1674 Vibration
1022 Visible alarm, none
2283 Voice prompts, inaudible
2282 Voice prompts, none
1675 Volume accuracy
1634 Volume fluctuations, tidal
1024 Warning alarm, error of
1025 Warning alarm, failure of
1676 Warning light, incorrect
1215 Warning or error message, failure to produce
1367 Washers, failure of lens
2315 Water purification system, failure of
1677 Water softener process, failure of
2295 Water softener regeneration cycle, mistiming of
1678 Water treatment
1187 Water, contamination of distilled
1682 Wavelength, incorrect
1679 Wedge filter problem
1680 Wedge, difficult to
1272 Will not support growth
2347 Wire(s), breakage of
2294 Wires, defective electrical
1107 Worn component(s)
1683 Zero, failure to

PART I, SUBPART B - NUMERIC LISTING OF EVENT CODES WITH THEIR CORRESPONDING EVENT TERM

CODE	TERM
1001	AC/DC, failure to run on
1002	Abnormal
1003	Absorption
1004	Accessories, incompatible
1005	Measurements, inaccurate
1006	Adaptor, failure of
1007	Agglutinate, failure to
1008	Air leak(s)
1009	Alarm, failure of arterial pressure
1010	Alarm, audible
1011	Alarm, delayed
1012	Alarm, failure to
1013	Alarm, false
1014	Alarm, defective
1015	Alarm, intermittent
1016	Alarm, low audible
1017	Alarm, failure of low flow
1019	Alarm, not audible
1020	Alarm, failure of fast heart rate
1021	Alarm, no lead
1022	Alarm not visible
1024	Alarm, error of warning
1025	Alarm, failure of warning
1026	Altitude variations
1027	Ambient temperature, changes in
1028	Anastomose, failure to
1029	Antenna, failure of
1031	Application problems
1032	Arcing at paddles
1033	Arm motion, unintended
1034	Blood gas measurements, abnormal
1036	Artifact
1039	Artificial
1040	Lens, aspherical
1041	Aspiration, excessive
1042	Aspiration, incomplete
1043	Augmentation, loss of
1044	Autofill, unable to
1045	Automatic injection system, incompatible
1046	Automatic injection system overinfusion
1047	Back-up, failure to
1048	Back-up, failure to convert to
1049	Balloon rupture
1050	Balloon asymmetrical
1051	Balloon burst
1052	Balloon leak(s)
1053	Balloon mushroomed
1054	Battery charger, defective
1055	Battery failure
1057	Battery, premature discharge of
1059	Bend
1060	Bicarbonate
1061	Lens, bifocal
1062	Biofilm coating
1063	Blank screen
1064	Bleed back
1065	Blockage
1067	Bolus mechanism failure
1068	Bond, failure to
1069	Device breakage
1070	Bubble(s)
1071	Burned
1073	Burrs, breakage of
1074	Burst
1075	Cathode ray tube (CRT) failure
1076	Cable break
1077	Calcification
1078	Calibration error
1079	Capacitive coupling
1080	Capture, intermittent
1081	Capture, failure to
1082	Carbon absorption
1083	Cautery
1084	Channeling
1085	Charge, failure to
1086	Charred
1087	Chemical reaction
1088	Circuit breaker tripped
1089	Circuit failure
1090	Clean, failure to
1091	Cleaning, inadequate
1092	Clearance
1093	Fiberoptic cleaver, failure of
1094	Clogged
1095	Clumping
1096	Coagulation
1097	Coefficient error
1098	Coiled
1099	Collapse
1100	Collimator design problem
1101	Colony forming units
1102	Compatibility
1103	Component(s), broken
1104	Component(s), detachment of
1105	Component(s) falling
1106	Component(s), overheating of
1107	Component(s), worn
1108	Component(s), incompatible
1110	Computer failure
1111	Computer hardware error
1112	Computer software error
1113	Concentrate
1114	Conduct, failure to
1115	Conductivity
1116	Connection error
1117	Connector pin failure

NUMERIC LISTING (continued)

CODE	TERM
1118	Contact lens, problem with trial set
1120	Contamination
1121	Continuity, intermittent
1122	Continuous
1123	Continuous firing
1124	Continuous mode failure
1125	Contraindicated patient
1126	Control settings incorrect
1127	Cool, failure to
1128	Coolant, contraindicated
1129	Cooling system, failure of
1130	Cooling, inadequate
1131	Corrode
1132	Counterbalance break
1133	Countershock, failure to deliver
1134	Couple, failure to
1135	Crack(s)
1136	Cross connection
1137	Cross reactivity
1138	Crush
1139	Cuff degeneration
1140	Cutoff point
1141	Cutter-torque-cable twisted or tangled
1142	Cycle, failure to
1143	Screw tapper, damaged
1144	Declotting
1145	Decoupling
1146	Suction, decreased
1147	Photomultiplier (PM) tube, defective
1148	Deflation, cause unknown
1149	Deflation difficulties
1150	Deflation due to capsulotomy
1151	Deflation due to damage from surgical instrument
1152	Deflation due to trauma
1153	Degradation
1154	Wound dehiscence
1155	Deionizer, failure of
1156	Delamination
1157	Deploy, difficult to
1158	Deploy, failure to
1159	Deprimed
1161	Design/structure problem
1162	Device energization, unintended
1165	Dialysate
1166	Dialyzer, failure of
1168	Disassembly
1169	Discharge, failure to
1170	Discolored
1171	Disconnect
1172	Disengaged
1175	Disinfect, failure to
1176	Disinfection, inadequate/improper
1177	Disintegrate
1178	Dislocated
1179	Dislodged
1180	Displacement
1181	Display misread
1182	Display, erratic
1183	Display, failure to
1184	Display, incorrect
1185	Disposable
1186	Dissection
1187	Distilled water, contaminated
1188	Dome collapse
1189	Dose calculation error
1191	Drift
1192	Dry, failure to
1193	EKG/ECG analysis, failure to perform
1194	Electro-magnetic interference (EMI)
1195	Elective removal
1196	Elective replacement
1197	Shock, electrical
1198	Electrical failure
1199	Electrode(s), failure of
1200	Electrode contact(s), problem with
1201	Electrode(s), degeneration of
1202	Electrode(s), fracture of
1203	Electrode(s), migration of
1204	Vessel or plaque, device embedded in
1205	Emergency power failure
1206	Emergency stop button or switch failure
1207	Emergency table stop failure
1208	Endoscopic accessory fire or melt
1209	Energy output to patient tissue incorrect
1210	Energy spectrum incorrect
1211	Energy, failure to deliver
1212	Entrapment
1213	Enzymatic cleaner, failure to remove
1214	Erosion
1215	Error or warning message, failure to produce
1216	Expiration date exceeded
1217	Explanted
1218	Explode
1219	External fiberoptic break
1220	Needle, extra
1221	Extraneous radiofrequency wave transmission
1222	Failsafe design failure
1223	Failure, intermittent
1224	False claim
1225	False-negative test result
1226	False output
1227	False-positive test result
1228	False readings
1229	Fiberoptic break/separation
1230	Fiberguide incompatibility
1231	Fiberoptic cladding material separation

CODE	TERM
1232	Lens, deposits on
1233	Filling problem
1234	Film cartridge ejection, unintended
1235	Film processing, inadequate
1236	Filter
1237	Filter leak(s)
1238	Filter break(s)
1242	Filter tear(s)
1243	Filter, assembly
1244	Filter, inadequate
1245	Fire
1246	Flaking
1247	Flammable
1248	Flowrate, restricted
1249	Flowrate, inaccurate
1250	Fluid leak(s)
1251	Flush, difficult to
1252	Flush, failure to
1253	Fogging
1254	Fold, difficult to
1255	Fold, failure to
1256	Footrest detachment
1257	Footrest break
1258	Footswitch failure
1259	Foreign material
1260	Fracture(s) of device/material
1261	Fragmentation
1262	Frayed
1263	Function indicator light(s), failure of
1264	Gain, inadequate
1265	Gas delivery system failure
1266	Gas output, improper
1267	Gel leakage
1268	Germicide
1269	Glass, shattered
1270	Gradient increase
1271	Grounding malfunctions
1272	Growth, will not support
1274	Handpiece break
1275	Handpiece detachment
1276	Handrest detachment
1277	Handrest break
1278	Haptic(s), bent
1279	Haptic(s), broken
1280	Haptic(s), detached
1281	Haptic(s), dislocated
1282	Haptic(s), fractured
1283	Head immobilizer failure
1284	Head motion, unintended
1285	Heat
1286	Heat, failure to
1287	Heating, inadequate
1288	Hemoconcentration
1289	Hemofiltration
1290	High flux rate
1291	Impedance, high
1293	Hole(s)
1294	Hose line occlusion
1295	Hose line rupture
1296	Hose mismatch
1297	Host-tissue reaction
1298	Hot oil leak
1299	Hybrid failure
1300	Hydraulic system failure
1301	Hydrogen peroxide sterilization, explosion during
1302	IV pole, detachment of parts from
1303	Ignited
1304	Image display error
1305	Image orientation incorrect
1306	Image resolution poor
1307	Imprecision
1309	Disc, incomplete opening of
1310	Inflation difficulties
1311	Overinfusion
1312	Injector system failure, no infusion
1313	Injector system failure, overinfusion of
1314	Injector system failure, underinfusion of
1316	Insertion difficulties
1317	Installation error
1318	Instructions, inadequate
1319	Instructions, incorrect
1320	Insulation degradation
1321	Insulation, detached
1322	Insulation, discolored
1323	Insulation failure
1325	Insulation, hole(s) in
1326	Insulation, none
1327	Interference
1328	Interference with monitoring device
1329	Interference with pacemaker
1330	Interlumen communication
1331	Interrogate, difficult to
1332	Interrogate, failure to
1333	Intimal dissection
1334	Intra-cavity procedure, fiberoptic break or fragmentation during
1335	Intraprocedure, fire or flash during
1336	Invagination
1337	Irrigate, inability to
1338	Kinetic
1339	Kink
1340	Knot
1341	LAL test (limulus amebocyte lysate)
1342	Laser nozzle separation
1343	Laser output above specifications
1344	Laser output, unintended
1345	Laser pulse timing error

NUMERIC LISTING (continued)

CODE	TERM
1346	Laser tip separation
1347	Lead(s), breakage of
1348	Lead(s), burn(s) from
1349	Lead(s), electrocution from
1350	Lead(s), fracture of
1351	Lead(s), shock from
1352	Leaflet disc escape
1353	Leaflet disruption
1354	Leak(s)
1355	Leak(s) from hydraulic bed system
1357	Leak, radiation
1358	Image reversal, left or right
1359	Lens, cloudy
1360	Lens, decentration of
1361	Lens, disc
1362	Lens, discoloration of
1363	Lens, malposition of
1364	Lens, opacification of
1365	Lens, repositioning of
1366	Lens, vaulting
1367	Lens washers, failure of
1368	Linear
1369	Lockout mechanism failure
1370	Looping
1371	Connection(s), loose
1372	Loose
1373	Lubrication
1374	Milliamps (MA) rate, unable to increase
1375	Magnet failure
1376	Magnet mode discrepancy
1377	Magnet quench, unintended
1378	Magnetic interference
1379	Maintain, failure to
1381	Markings unclear
1382	Markings, none
1383	Measurements, incorrect
1384	Mechanical failure
1385	Melts
1387	Abrasion from instrument/object
1388	Membrane, breakage of
1390	Membrane leak(s)
1391	Membrane tear(s)
1392	Meter
1393	Method, improper/incorrect
1395	Migration
1396	Mineralization
1397	Misapplication
1398	Misassembly
1399	Misconnection
1401	Misfocusing
1402	Mislabeled
1403	Mislocation
1404	Misplacement
1405	Moisture damage
1406	Monitor display alarm, failure of
1407	Monitor failure
1408	Monitor, image quality poor
1409	Motor failure
1410	Motor drive unit (MDU) stalled or jammed
1411	Lens, multifocal
1412	Muscle stimulation
1413	Necrosis, pressure
1414	Needle, dull
1415	Needle, separation
1416	Needle, unsheathed
1417	Nicks, cuts or tears of dura or other tissues by device
1418	Non-linear
1419	Nonpyrogenic
1420	Nonstandard
1421	Nonsterility
1422	Normal
1423	Occlusion
1424	Occlusion, incorrect
1425	Odor
1426	Opaque
1428	Ossification
1429	Collision, unintended
1430	System motion, unintended
1431	Output energy incorrect
1432	Output above specifications
1433	Output, high
1434	Output, low
1435	Output, none
1436	Overcorrection
1437	Overheat
1438	Oversensing
1439	Pace, failure to
1440	Pacer found in back-up mode
1441	Pacing asynchronously
1442	Pacing inadequately
1443	Pacing intermittently
1444	Packaging, unsealed
1445	Pallet break
1446	Pallet crack(s)
1447	Pannus formation
1448	Paramagnetic
1449	Parameter calculations, incorrect
1450	Paravalvular leak(s)
1451	Particulates
1454	Peeling
1455	Percutaneous
1456	Performance
1457	Leak(s), perivalvular
1458	Phantom problem
1459	Pierce
1460	Pitting
1461	Plugged

CODE	TERM
1462	Plunge
1463	Pocket stimulation
1464	Poor gas exchange
1465	Port leak(s)
1466	Portable mode, failure to run on
1467	Positioning difficulties
1469	Potency
1470	Potentiometer readings, high
1471	Potentiometer readings, low
1473	Power, miscalculation of
1474	Power surge
1475	Power, loss of
1476	Power-up, failure to
1477	Pre/post-pumping problems
1478	Precipitate
1479	Precision
1480	Premature end-of-life (EOL) indicator
1483	Premature ERI (elective replacement indicator)
1484	Premature deployment
1485	Premature explantation
1486	Premature system activation
1487	Prep, difficult to
1488	Prep, failure to
1489	Pressure sensor failure
1490	Pressure, decreased
1491	Pressure, increased
1492	Prime, failure to
1493	Probe failure
1494	Product, incorrect
1495	Programming calculations, incorrect
1496	Program, difficult to
1497	Program, failure to
1498	Pulmonary embolism
1500	Pump speed, decreased
1501	Pump speed, increased
1502	Pump, failure to
1503	Pumping, stopped
1504	Puncture
1505	Pyrogenic
1506	Quality, unsatisfactory or poor
1507	R on T phenomenon
1508	Radiation delivered to incorrect body area
1509	Radiation exposure, unintended
1510	Radiation overdose
1511	Radio signal problems
1512	Accuracy rate
1513	Rate modulated pacing sensor, failure of
1514	Reaction
1516	Readings, unable to obtain
1517	Recalibrate, failure to
1518	Recannulation
1519	Receiver failure
1520	Receiver stimulator unit, failure of
1521	Record, failure to transmit
1522	Reflux
1523	Regenerate
1524	Rejection
1525	Device remains activated
1526	Device remains implanted
1527	Device, or device fragments remain in patient
1528	Removal difficulties
1529	Repair
1530	Replace
1531	Reservoir
1532	Reset, failure to
1533	Resistance, inadequate
1534	Resistance, loss of
1535	Results incorrect
1536	Retract, failure to
1537	Reuse
1538	Reverse osmosis
1539	Rhythm, failure to analyze
1540	Rhythm, failure to convert
1541	Rhythm, failure to diagnose
1542	Rhythm, failure to override
1543	Rhythm, incorrect interpretation of
1544	Rigid
1545	Runaway
1546	Rupture
1547	Rupture due to capsulotomy
1548	Rupture, cause unknown
1549	Rupture, fold or crease due to
1550	Rupture due to damage from surgical instrument
1551	Rupture due to stress from capsular contracture
1552	Rupture due to trauma
1553	Saline, use of homemade
1554	Salt tablet(s), use of
1555	Seal, incorrect
1556	Sediment filter problems
1557	Self-activation/keying
1558	Sensing intermittently
1559	Sensing, none
1560	Sensitivity
1561	Sensor problems
1562	Separates
1563	Service, failure to
1564	Service, inadequate
1565	Shaft break
1566	Shaft, split
1567	Shelf life exceeded
1568	Shielding failure
1569	Shielding, inadequate
1570	Shipping damage or problem
1571	Shock counters, resetting of

CODE	TERM
1572	Shock, failure to advise
1573	Shock, failure to deliver
1574	Shock, inappropriate
1575	Short fill
1576	Shoulder rest, detachment of
1577	Shoulder support, detachment of
1578	Shunts, failure of
1579	Shutter failure
1580	Side rails, failure of
1581	Input signal, failure to read
1582	Signal, failure to select
1583	Size, incorrect
1584	Slippage
1585	Smoke
1586	Source, detachment from
1587	Source, leak(s) from
1588	Source, incorrect
1589	Specificity
1590	Speech processor failure
1591	Spillage, accidental
1592	Spring loading mechanism problem
1593	Stacking breaths
1594	Steering wire problem
1595	Sterility
1596	Sterilization, inadequate
1597	Sticking
1599	Stops intermittently
1600	Storage, inadequate
1601	Stretched
1602	Strut fracture
1603	Stuck in inspiratory or expiratory phase
1604	Suction, increased
1605	Superheat
1606	Supplier
1607	Suture line disruption
1608	Suture line separation
1609	Synchronization, inaccurate
1610	Syncope
1611	Syringe drive problem
1612	Syringe, defective
1613	Syringe, hole(s) in
1614	Syringe markings inaccurate
1615	Alarm system, failure of message-battery status
1616	Alarm system, failure of message-check electrode
1617	Alarm system, failure of message-leads off
1618	Alarm system, failure of message-service
1619	System fails to activate
1620	Alarm system, failure of check-catheter
1621	Alarm system, failure of gas-leak/loss
1622	Table angulation, unintended
1623	Table incrementation incorrect
1624	Table top motion, unintended
1625	Table break
1626	Table collapse
1627	Tap water, use of
1628	Tears, rips, holes in device, device material
1629	Telemetry discrepancies
1630	Test strips, incompatible
1631	Therapeutic results, unexpected
1632	Threader failure
1633	Threshold, loss of
1634	Tidal volume fluctuations
1635	Timer failure
1637	Timer malfunction
1638	Tip breakage
1639	Tomographic pallet crack(s)
1640	Lens, toric
1641	Torqued
1642	Tracking
1643	Training, inadequate
1644	Transducer overheating
1645	Transducer probe overheating
1646	Transducer failure
1647	Transmitter failure
1648	Trocar failure
1649	Trocar/fiber incompatibility
1650	Trocar/instrument incompatibility
1651	Tube(s), exploding of
1652	Tube(s), shattering of
1653	Tube(s), splitting of
1654	Tubing, incorrect placement of
1655	Twisting
1656	Ultrafiltration
1657	Ultraviolet
1658	Ultraviolet absorbing
1659	Uncoiled
1660	Undercorrection
1661	Undersensing
1662	Unit inactivated
1663	Device, inoperable
1664	Unravel
1665	Source, unretracted
1667	Unstable
1668	Unwrap, difficult to
1669	Unwrap, failure to
1670	Device, incorrect care/use of
1671	Vacuum, loss of
1672	Valve(s), failure of
1673	Valve(s), sticking
1674	Vibration
1675	Volume accuracy
1676	Warning light, incorrect
1677	Water softener process, failure of
1678	Water treatment
1679	Wedge filter problem
1680	Wedge, difficult to

CODE	TERM
1681	Screw head(s), incorrect
1682	Wavelength, incorrect
1683	Zero, failure to
1684	AIDS, acquired immunodeficiency syndrome
1685	Pain, abdominal
1688	Abortion
1689	Abrasion
1690	Abscess
1692	Achalasia
1693	Shock, acoustic
1694	Acoustic trauma
1695	Adhesion(s)
1696	Adult respiratory distress syndrome, (ARDS)
1697	Air embolism
1698	Airflow, restricted
1699	Airway obstruction
1701	Allergic reaction
1702	Amputation
1703	Shock, anaphylactic
1704	Anaphylaxis
1705	Anastomosis
1706	Anemia
1707	Anesthesia, insufficient, light or patchy
1708	Aneurysm
1710	Angina
1711	Anoxia
1713	Antibiotics, reaction to
1714	Anticoagulation
1715	Aortic insufficiency
1716	Aortic regurgitation
1717	Aortic stenosis
1718	Apgar score, decreased or low
1719	Apheresis
1720	Apnea
1721	Arrhythmia
1722	Arteriosclerosis
1723	Arthritis
1724	Arthritis, rheumatoid
1725	Aspiration
1726	Asthma
1727	Asystole
1728	Atherosclerosis
1729	Atrial fibrillation
1730	Atrial flutter
1731	Atrial tachycardia
1732	Autoimmune disease
1733	Autoimmune reaction
1734	Automatic injection system, failure to infuse
1735	Infection, bacterial
1736	Biliary cirrhosis
1738	Bleeding
1739	Bleeding, cerebral
1741	Bleeding, intracranial
1742	Blindness
1743	Blister(s)
1744	Bloating
1745	Contamination from blood/fluids
1746	Blood in tubing
1747	Blood pooling
1749	Transfusion with incompatible blood
1750	Erosion
1751	Bradycardia
1752	Bronchitis
1754	Bruise
1755	Burn, radiation
1756	Burn, bowel
1757	Burn(s)
1758	Calcification
1759	Cancer, breast
1760	Cancer, other
1761	Capsular contracture
1762	Cardiac arrest
1763	Myocardial contusion
1764	Cardiomyopathy
1765	Cardiopulmonary arrest
1766	Cataract
1767	Cataract, induced
1768	Cellulitis
1770	Cerebrovascular accident, (CVA)
1771	Cerebral, infarction
1772	Cerebrospinal fluid leakage
1773	Cervical changes
1774	Cesarean section (c-section)
1775	Chemosis
1776	Chest pain
1777	Chorioamnionitis
1778	Coagulation
1779	Coagulopathy
1781	Comatose
1782	Congenital defect/deformity
1783	Congestive heart failure
1784	Conjunctivitis
1785	Conjunctivitis, giant papillary
1786	Connective tissue disease
1787	Contusion
1788	Core temperature rise
1789	Corneal abrasion
1790	Corneal decompensation
1791	Corneal edema
1792	Cornea, perforation of
1793	Corneal scar
1794	Corneal touch
1795	Corneal transplant
1796	Corneal ulcer
1797	Crushing injury
1798	Cyanosis

CODE	TERM
1799	Cyclitis
1800	Cyst(s), formation of
1801	Deafness
1802	Death/expired
1803	Debris, bone shedding
1804	Debris, metal shedding
1805	Decreased apgar
1806	Degeneration
1807	Dehydrated
1808	Dementia
1809	Deposits
1810	Device induced
1811	Diarrhea
1812	Purulent discharge
1813	Disseminated intravascular coagulation (DIC)
1814	Dry eye(s)
1815	Dysphagia
1816	Dyspnea
1817	EKG/ECG changes
1818	Ecchymosis
1819	Ectopic pregnancy
1820	Edema
1822	Edema, macular
1823	Edema, microcytic
1824	Edema, stromal
1826	Electro-mechanical dissociation
1827	Electrocution
1829	Embolism
1830	Embolus
1831	Emotional changes
1832	Emphysema, pulmonary
1833	Encephalopathy
1834	Endocarditis
1835	Endophthalmitis
1838	Enzyme elevation, cardiac
1839	Eructate
1840	Erythema
1841	Exsanguination
1842	Extravasation
1843	Extreme exhaustion
1844	Extrusion
1845	Eye injury
1846	Facial nerve paralysis
1847	Fainting
1848	Fall
1849	Fatigue
1850	Feeding problems
1851	Asphyxia
1852	Fetal brain injury
1854	Fetal core temperature rise
1855	Death, intrauterine fetal
1856	Fetal distress
1857	Fetal scalp laceration(s)
1858	Fever
1859	Fiberoptic fragments, unretrieved in body
1860	Fibromyitis
1861	Fibrosis
1862	Fistula
1863	Osseointegrate, failure to
1864	Flashers
1865	Flatus
1866	Floaters, vitreous
1868	Foreign body reaction
1869	Foreign body sensation
1870	Fracture(s)
1871	Urgency
1872	Fungus
1873	Gangrene
1874	Gastritis
1875	Glaucoma
1876	Granuloma
1877	Hair loss
1878	Haze
1879	Head injury
1880	Headache
1881	Hearing impairment
1882	Hearing loss
1883	Heartburn
1884	Hematoma
1885	Hemodialysis
1886	Hemolysis
1887	Hemoptysis
1888	Hemorrhage
1889	Hemorrhage, cerebral
1890	Hemorrhage, extradural
1891	Hemorrhage, intracranial
1892	Hemorrhage, intraventricular
1893	Hemorrhage, subarachnoid
1894	Hemorrhage, subdural
1895	Hemostasis
1896	Hemothorax
1897	Hepatitis
1898	Herpes
1899	Hiccups
1900	Hives
1901	Hyaloid face, rupture of
1903	Hyperbilirubinemia
1904	Hyperemia
1905	Hyperglycemia
1906	Hyperplasia
1907	Hypersensitivity
1908	Hypertension
1909	Hyperthermia
1910	Hyperventilation
1911	Hyphema
1912	Hypoglycemia
1913	Hypopyon

CODE	TERM
1914	Hypotension
1915	Hypothermia
1916	Hypoventilation
1917	Shock, hypovolemic
1918	Hypoxia
1919	IUD (intrauterine contraceptive device), removal of
1920	IV catheter pull out
1922	Iatrogenic lesion
1923	Idioventricular rhythm
1924	Implant, failure of
1925	Impotence
1926	Insufficiency, valvular
1927	Incompetent cervix
1928	Incontinence
1930	Infection
1931	Infiltration
1932	Inflammation
1933	Infection, intraocular
1934	Lens (IOL), dislocated intraocular
1935	Lens (IOL), migration of intraocular
1936	Intraocular pressure (IOP), delayed, uncontrolled
1937	Intraocular pressure rise, (IOPR)
1938	Intravasation
1940	Iritis
1941	Irritation
1942	Ischemia
1943	Itching
1944	Keratitis
1945	Keratitis, acanthamoeba
1946	Laceration(s)
1947	Left ventricular dysfunction
1948	Left ventricular failure
1949	Left ventricular hypertrophy
1950	Lesion
1951	Lesions in the target points
1952	Ligament(s), damage to
1953	Liver contusion
1954	Liver dysfunction
1955	Liver laceration(s)
1956	Lupus
1957	Cytomegaloviral retinitis
1958	Memory loss
1959	Menstrual irregularities
1960	Microcyst(s)
1961	Microperforation(s)
1962	Miscarriage
1963	Mitral insufficiency
1964	Mitral regurgitation
1965	Mitral stenosis
1966	Muscle spasm(s)
1967	Muscle weakness
1968	Muscular rigidity
1969	Myocardial infarction, (MI)
1970	Nausea
1971	Necrosis
1972	Necrosis of flap tissue
1974	Neonatal deformities
1975	Neonatal hearing impairment
1976	Neonatal hearing loss
1978	Neovascularization
1979	Nerve damage
1980	Nerve stimulation, undesired
1981	Neural tissue damage
1982	Neurological deficit/dysfunction
1983	Neuropathy
1984	Occlusion
1985	Reocclusion
1986	Optical nerve damage
1987	Organ(s), perforation of
1988	Overdose
1989	Overmedicated
1990	Oversedated
1991	Overstimulation
1992	Polymyositis
1994	Pain
1995	Painful stimulation
1997	Paralysis
1998	Paresis
1999	Peeling
2000	Pelvic inflammatory disease, (PID)
2001	Perforation
2002	Peripheral vascular disease
2003	Peritoneal laceration(s)
2004	Phlebitis
2009	Pleomorphism
2010	Pleural effusion
2011	Pneumonia
2012	Pneumothorax
2013	Pocket erosion
2014	Megophthalmos
2015	Positive antinuclear antibodies (ANA)
2017	Procedure, improper/incorrect
2019	Pulmonary dysfunction
2020	Pulmonary edema
2021	Pulmonary infarction
2022	Pulmonary insufficiency
2023	Pulmonary regurgitation
2024	Pulmonary stenosis
2025	Punctured blood vessels
2026	Pupillary block
2027	Pus
2028	Pyrogenic
2031	Radiation underexposure
2032	Range of motion, loss of
2033	Rash
2034	Raynaud's phenomenon

NUMERIC LISTING (continued)

CODE	TERM
2035	Reaction, local
2036	Reaction, systemic
2038	Red eye(s)
2039	Renal disease (ESRD), end stage
2041	Renal failure
2042	Surgical procedure, repeated
2043	Respirator, detachment from
2044	Respiratory arrest
2045	Respiratory distress
2046	Respiratory distress syndrome (RDS) of newborns
2047	Retina, detached
2048	Retina, damage to
2049	Retina, degeneration of
2050	Retina, tear(s) in
2051	Retrograde
2052	Retrograde flow
2053	Rheumatic heart disease
2054	Right ventricular dysfunction
2055	Right ventricular failure
2056	Right ventricular hypertrophy
2058	Staphyloccus aureus
2059	ST segment elevation
2060	Scar tissue
2061	Scarring
2062	Scleroderma
2063	Seizures
2064	Seizures, focal motor
2065	Sensitivity
2066	Sensitization
2067	Sepsis
2068	Shock, septic
2069	Seroma
2070	Severed digit(s), (finger or toe)
2071	Venereal disease (VD)
2072	Shock
2073	Sjogren's syndrome
2074	Skin discoloration
2075	Skin erosion
2076	Skin irritation
2077	Fracture, skull
2078	Ventricle, abnormality of
2079	Soreness
2081	Spinal injury
2082	Spotting
2083	Sprain
2084	Strangulation
2085	Stricture
2086	Stroke
2087	Subepithelial infiltration
2088	Suffocation
2089	Sunset syndrome
2091	Swelling
2092	Swollen glands
2093	Swollen lymph nodes
2094	Synovitis
2095	Tachycardia
2096	Body temperature, elevated
2097	Tentorial tears
2098	Toxins in children
2099	Therapeutic effects, unexpected
2100	Thrombosis
2101	Thrombus
2102	Thyroid problems
2103	Tinnitus
2104	Tissue damage
2105	Tissue failure
2106	Tissue, breakdown of optical
2107	Torsades-de-Pointes
2108	Toxic shock syndrome, (TSS)
2109	Transient ischemic attack
2110	Transplant of organ/tissue
2111	Tricuspid insufficiency
2112	Tricuspid regurgitation
2113	Tricuspid stenosis
2114	Twiddler's syndrome
2115	UGH (uveitis-glaucoma-hyphema) syndrome
2116	Ulceration
2117	Under no medication
2118	Under no sedation
2119	Urinary retention
2120	Infection, urinary tract
2121	Uterine perforation
2122	Uveitis
2123	Vaginal discharge
2124	Vaginal mucosa damage
2126	Vasoconstriction
2127	Vasodilatation
2128	Vasospasm
2129	Venipuncture
2130	Ventricular fibrillation
2131	Ventricular flutter
2132	Ventricular tachycardia
2133	Ventriculomeglia
2134	Vertigo
2135	Vessels, perforation of
2136	Virus
2137	Vision, blurring of
2138	Vision, impaired
2139	Vision, loss of
2140	Visual disturbances
2142	Vitreous fluid, loss of
2143	Vitreous fluid, blood in
2144	Vomiting
2145	Weakness
2146	Burning sensation
2147	Calcium deposit(s)
2149	Electro-static discharge

NUMERIC LISTING (continued)

CODE	TERM
2150	Epithelial marsupialization
2151	Film processor failure
2152	Great vessel perforation
2153	Hot flashes
2154	Implant extrusion
2155	Improved patient condition
2156	Immuno-deficiency
2157	Interlock(s), failure of
2158	Lens aberration, distortion of
2159	Misdiagnosis
2160	Motion detector failure
2161	Muscular tics
2162	Nipple sensation, changes in/loss of
2163	Noise
2164	Phosphene visualization
2165	Phototoxicity
2166	Radiation underdose
2167	Safety interlock(s) inadequate
2168	Seizures, grand-mal
2169	Seizures, petit-mal
2170	Suction failure
2171	Tingling
2172	Twitching
2173	Corneal implant
2174	Infiltrates
2177	Surgery, prolonged
2178	Staining
2181	Vitritis
2182	Underinfusion
2183	Fitting problems
2184	Lens replacement
2186	Headache, lumbar puncture
2187	Jaundice
2188	Uremia
2189	Collagen disease
2191	Chills
2192	Concussion
2193	Cramp(s)
2194	Dizziness
2195	Dysphasia
2196	Electrolyte imbalance
2197	HIV, human immunodeficiency virus
2198	Mediastinal shift
2199	No consequences or impact to patient
2200	Other (for use when an appropriate patient code cannot be identified)
2201	Leak(s), perivalvular
2202	Unknown (for use when the patient's condition is not known)
2203	Other (for use when an appropriate device code cannot be identified)
2204	Unknown (for use when the device problem is not known)
2205	Perforation
2206	Heart failure
2207	Toxemia
2208	Rupture
2209	Asphyxia, fetal
2210	Hypoxia, fetal
2211	Abortion, artificial
2212	Abortion, complete
2213	Abortion, incomplete
2214	Abortion, induced
2215	Abortion, missed
2216	Abortion, therapeutic
2217	Amnionitis
2218	Anaphylactoid
2219	Brain injury
2220	Cytomegalovirus (CVM)
2221	Convulsion
2222	Convulsion, clonic
2223	Convulsion, tonic
2224	Dementia, dialysis
2225	Discharge
2226	Cardiac tamponade
2227	Halo
2228	Clouding, central corneal
2229	Blinking, excessive
2230	Blurring
2231	Corneal infiltrates
2232	Microcysts, epithelial
2233	Corneal sensitivity
2234	Overwear syndrome
2235	Tearing, excessive
2236	Endotoxin
2237	Chronic obstructive pulmonary disease, (COPD)
2238	Myalgia
2239	First use syndrome
2240	Hernia
2241	Wheal(s)
2242	Hypernatremia
2243	Hypovolemia
2244	Infection, direct
2245	Infection, indirect
2246	Infection, pyrogenic
2247	Infection, subclinical
2248	Infection, viral
2249	Migration
2250	Nonpyrogenic
2251	Sneezing
2252	Peritonitis
2253	Dermatomyositis
2254	Reaction, pyrogenic
2255	Radiodermatitis
2256	Radiation sickness syndrome
2259	Regurgitation
2260	Seizures, focal

NUMERIC LISTING (continued)

CODE	TERM
2261	Seizures, absence
2262	Shock, cardiogenic
2263	Stenosis
2264	Shock, insulin
2265	Shock, neurogenic
2266	Shock, postoperative
2267	Shock, surgical
2268	Shock, traumatic
2269	Toxoplasmosis, acquired
2270	Toxoplasmosis, congenital
2271	Therapeutic response, decreased
2272	Therapeutic response, increased
2273	Teratogenic effects
2274	Ulcer
2275	Urinary frequency
2276	Nonresorbable materials, unretrieved in body
2277	Sinus, perforation of
2278	Urticaria
2279	Hemolytic anemia
2280	Prompts, inappropriate
2281	Prompts will not clear
2282	Prompts, no voice
2283	Prompts, inaudible voice
2284	Damage, internal/external
2285	Impedance, low
2286	Algorithms, inconsistent
2287	Shock, intermittent
2288	Charge, aborted
2289	Arcing at electrodes
2290	Blood gas measurements, erroneous
2291	Semiautomatic code, failure to override
2292	Components, defective
2293	Sensing, invalid
2294	Electrical wires, defective
2295	Water softener regeneration cycle, mistiming of
2296	Temperature probe, loose
2297	Bubble detector, failure of
2298	Valve(s), defective
2299	Tube(s), defective
2300	Air eliminator, defective
2301	Seal, defective
2302	Cable, defective
2303	Contamination, bacterial
2304	Stopcock valve, failure of
2305	Burn hole(s)
2306	Components, missing
2307	Automatic injection system underinfusion
2308	Filtration process, inadequate
2309	Rinsing, improper
2310	Specialty beds, rips/tears in
2311	Out-of-box failure
2312	Packaging, incomplete/missing
2313	Radiation overexposure
2314	Radiofrequency interference (RFI)
2315	Water purification system, failure of
2316	Fungus
2317	Blood contaminated device
2318	Blood pooling
2319	Cardiac enzyme evaluation, erroneous
2320	Implant, removal of
2321	Implant, repositioning of
2322	Implant, reprogramming of
2323	Surgical graft, failure of
2324	Solder joint failure
2325	Residue
2326	Pressure sores/ulcers
2327	Entrapment
2328	Anxiety
2329	Distress
2330	Discomfort
2331	Complaint, ill-defined
2332	Blockage
2333	Toxicity
2334	Cardiac insufficiency
2335	Regurgitation, valvular
2336	Stroke syndrome
2337	Transfusion of blood products
2338	Deliver, failure to
2339	Delivery, inaccurate
2340	Infuse, failure to
2341	Infusion, intermittent
2342	Overdelivery
2343	Underdelivery
2345	Electro-magnetic interference (EMI), compatibility/incompatibility
2346	Tube(s), buckling of
2347	Wire(s), breakage of
2348	Injury
2349	Fracture, hip
2351	Fracture, arm
2352	Hypoesthesia
2353	Hypoesthesia, arm/hand
2354	Hypoesthesia, foot/leg
2355	Arthralgia
2356	Joint swelling
2357	Surgical procedure
2358	Scar excision
2359	Malaise
2360	Disfigurement
2361	Depression
2362	Peroneal nerve palsy
2363	Dyskinesia
2364	Diabetic ketoacidosis
2365	Foreign body, removal of
2366	Laparotomy
2367	Pharyngitis
2368	Sedation

CODE	TERM
2369	Fracture, delayed union
2370	Mammogram, abnormal
2371	Disability
2372	Apicectomy
2373	Joint disorder
2374	Joint dislocation
2375	Fasciitis
2376	Mitral valve replacement
2377	Osteolysis
2378	Healing, impaired
2379	Device failure
2381	Laparoscopic sterilization
2382	Meter failure
2383	Internal fixation, revision of
2384	Lens implant
2385	Packaging, tears, rips, holes in
2386	Alarm, failure of high inspiratory pressure
2387	Alarm, failure of low inspiratory pressure
2388	Pain relief, inadequate
2389	Meningitis
2390	Arachnoiditis, spinal
2391	Pressure, insufficient
2392	Reintubate
2393	Tracheostomy
2394	Brain damage
2395	Ventilator dependent
2396	Sore throat
2397	Lung, overinflation of
2398	Esophagus, laceration(s) of
2399	Esophagus, perforation of
2400	Resuscitation
2401	Breathing difficulties
2402	Extubate
2403	Reinfusion
2404	Overfill
2405	Syringe markings, incorrectly placed
2406	Identified diagnosis
2407	Dull
2408	Osseointegration, loss of
2409	Malfunction
2410	Miscalibration
2411	Nonspecific
2412	Dissatisfaction
2413	Leaflet fracture
2414	Reaction
2415	Numbness
2416	Collapse
2417	Coma
2418	Consciousness, loss of
2419	Infection, fungal
2420	Infection, upper respiratory tract
2421	Irritability
2422	Obstruction
2423	Obstruction
2424	Patch test, abnormal results of
2425	pH, low
2426	pH, high
2427	Teeth, sensitivity of
2428	Fracture, tooth
2429	Encephalitis
2430	Forced expiratory volume (FEV), decreased
2431	Forced expiratory volume (FEV), increased
2432	Spinal cord injury
2433	Pain, neck
2434	Stiffness, neck
2435	Peak expiratory flowrate, decreased
2436	Peak expiratory flowrate, increased
2437	Bronchopneumonia
2438	Breast neoplasm
2439	Breast lumps
2440	Calibrate, failure to
2441	Nipple ulceration
2442	Reaction, injection site
2443	Skin inflammation
2444	Sweating
2445	Vitreous, detachment of
2446	Wound infection, post-operative
2447	Wound infection, post-traumatic
2448	Paraplegia
2449	Quadriplegia
2450	Blood glucose, low
2451	Blood glucose, high
2452	Diaphoretic
2453	Cut(s)
2454	Cut(s)
2455	Contamination, chemical
2456	Test results, inaccurate
2457	Test results, high
2458	Test results, low
2459	Readings, high
2460	Readings, low
2461	Body temperature, decreased
2462	Needle stick/puncture
2463	Chest tightness/pressure
2464	Choking
2465	Labor, premature
2466	Nasal obstruction
2467	Palpitations
2468	Pallor
2469	Pulse, irregular
2470	Myocarditis
2471	Mitral valve prolapse
2472	Aortic valve replacement
2473	Tricuspid valve replacement
2474	Pulmonary valve replacement
2475	Prolapse
2476	Heart valve repair
2477	Oxygen saturation, low

CODE	TERM
2478	Oxygen saturation, high
2479	Pulmonary arterial wedge pressure, low
2480	Pulmonary arterial wedge pressure, high
2481	Pulmonary arterial wedge pressure, normal
2482	Respiratory acidosis
2483	Respiratory alkalosis
2484	Respiratory failure
2485	Respiratory rate, decreased
2486	Respiratory rate, increased
2487	ST segment depression
2488	Blood pressure, high
2489	Blood pressure, low
2490	Unresponsive

PART I, SUBPART C - DEFINITIONS FOR EVENT TERMS LISTED NUMERICALLY BY EVENT CODE

CODE	DEFINITION
1003	The uptake of substances into or across tissues; e.g. skin, intestine, and kidney tubules. In radiology, the taking up of energy by matter with which the radiation interacts.
1007	The clumping together in suspension of antigen-bearing cells, microorganisms, or particles in the presence of specific antibodies.
1027	The temperature of the surrounding medium, such as gas or liquid, which comes into contact with the apparatus.
1028	Failure to create an opening by surgical, traumatic, or pathological means between two normally separate spaces or organs.
1036	Anything in a graphic record or medical image that is caused by the technique used to produce the record and is not a natural occurrence but merely incidental.
1040	A lens in which one or both surfaces are not spherical, so designed to minimize certain optical aberrations.
1041	The removal by suction of excess fluid or gas from a body cavity.
1042	The removal by suction of excess fluid or gas from a body cavity.
1043	Loss of size, degree or effect.
1050	Lack of proportion; not symmetrical.
1060	A salt of carbonic acid; an acid carbonate, as sodium bicarbonate.
1061	Lens having two portions of different focal power.
1064	Backflow of blood and/or fluid/solution.
1073	A thin, ragged fin left on the edge of a piece of metal by a cutting or punching tool.
1077	A calcified substance or part.
1079	Use of a capacitor to transfer energy from one circuit to another.
1080	Ineffective and inconsistent depolarization of the heart resulting from the electrical stimulus of the pacemaker.
1081	Inability to achieve effective and consistent depolarization of the heart resulting from the electrical stimulus of the pacemaker.
1082	Use of activated carbon to remove a variety of organic chemicals in the water used in hemodialysis.
1083	The application of a caustic substance, a hot instrument, an electric current or other agent to destroy tissue.
1084	Blood leakage around the catheter upon insertion into the patient.
1086	To scorch or become scorched.
1095	The aggregation of particles, such as bacteria, into irregular masses.
1096	To congeal, solidify, thicken, curdle.
1097	Measurement value associated with dialyzer clearance.
1101	A collection or group of bacteria in a culture derived from the increase of an isolated single organism or group of organisms.
1113	Chemicals, either liquid or powder, used to make dialysate in hemodialysis.
1115	Measurement of the ionic concentration of a solution used in dialysis.
1121	Continuous effective contact of all components of an electric circuit to give it high conductance by providing low resistance.
1123	Fire conducted at a normal rate without interruption, for application of adjustment corrections or for other causes.
1124	Continuous failure of one of several alternate conditions or methods of operation.
1125	Any special symptom or circumstance that renders the use of a remedy or the carrying out of a procedure inadvisable, usually because of the risk.
1133	A high intensity direct current shock delivered to the heart to interrupt ventricular fibrillation and restore synchronous electrical activity.
1137	The degree to which an antibody or antigen participates in cross reactions.
1139	Chemical and/or material (heart valve or tracheal) deterioration.
1140	The point at which there is a transition from spiral flow in the housing of a centrifugal fan to a straight line flow in the connected duct.
1145	Preventing transfer or feedback of energy from one circuit to another.
1147	A photo tube with one or more dynodes between its photocathode and the output electrode.
1153	The reduction of a chemical compound to one less complex, as if by splitting off one or more groups.
1154	Separation of the layers of a surgical wound; it may be partial and superficial only, or complete with disruption of all layers.

DEFINITIONS (continued)

1155 Removes cations and anions used in water treatment systems for hemodialysis.
1156 Division into separate layers.
1157 Spread out, utilize or arrange.
1165 That part of a mixture that passes through a dialyzing membrane.
1166 The apparatus for performing dialysis; a membrane used in dialysis.
1191 Slow movement away from the normal or orginal position.
1194 Interference, generally at radio frequencies, that is generated inside systems, as contrasted to radio-frequency interference coming from sources outside a system.
1197 The immediate effects produced by the passage of an electric current through any part of the body, e.g., painful stimulation of nerves or tetanic contractions of muscles.
1204 Device and/or fragments of device are embedded in patient's vessel and/or plaque.
1212 Device and/or accessories caught within patient vasculature or tissue.
1219 Coated with glass or plastic fibers having special optical properties.
1225 A test result which erroneously excludes an individual from a specific diagnostic or reference group, due particularly to insufficiently exact methods of testing.
1227 A test result which erroneously assigns an individual to a specific diagnostic or reference group, due particularly to insufficiently exact methods of testing.
1268 An agent that kills pathogenic microorganisms.
1270 Rate of change of temperature, pressure, or other variable as a function of distance, time, etc.
1278 A haptic is a loop or foot of an intraocular lens implant that supports the lens against the iris.
1288 An increase in the concentration of blood cells resulting from the loss of plasma or water from the blood stream.
1289 A device that corrects abnormalities of the blood by bulk convection of solutes and water through a semipermeable membrane.
1290 The rate per unit of area at which water passes through a semi-permeable membrane, such as those used for ultrafiltration or reverse osmosis.
1291 The opposition to the flow of an alternating current, which is the vector sum of ohmic resistance plus additional resistance, if any, due to induction, to capacity or to both.
1297 Growth of tissue in or around a foreign body as the body's antibody response to the foreign body.
1301 Hydrogen peroxide sterilization is a method of sterilizing soft contact lenses in a peroxide solution.
1320 Loss of continuity of insulation via wear, split, crack and/or breach.
1328 See also: Electro-magnetic interference (EMI) codes.
1329 See also: Electro-magnetic interference (EMI) codes.
1330 Two or more lumens intercrossed.
1331 To give or send out a signal to a transponder or computer for triggering an appropriate response.
1333 Pertaining to the inner layer of the blood vessels.
1336 The ensheathing, infolding or insertion of a structure within itself or another.
1338 Relating to motion or movement.
1341 An extract of blood cells from the horseshoe crab is exposed to a blood sample from a patient to test for gram negative endotoxin.
1352 Leakage of blood around leaflet disc.
1353 A separation of the cusp of a heart valve.
1364 The development of opacity as of the cornea or lens.
1374 A milliamps is a measurement of the flow of electricity.
1376 Alternation in the activation of a pulse generator reed switch by a magnet.
1377 Any type of interference that reduces the intensity of fluorescence.
1411 A lens with various dioptric powers, such as bifocal, trifocal or a progressive lens.
1413 Death of tissue due to external pressure.
1419 Free of fever producing substances.
1423 The act of closing or the state of being closed; an obstruction.
1426 Impervious to light; not translucent or only slightly so.
1428 The formation of bone or of a bony substance; the conversion of fibrous tissue or of cartilage into bone or a bony substance.

DEFINITIONS (continued)

1429 Collision occurring with the patient or other room components caused by device failure or unintended system motion.

1430 Any motion of the system or components that was not initiated by the user.

1438 The pacemaker does not release a stimulus when it is needed because it senses intracorporeal and extracorporeal signals as intrinsic cardial activity.

1441 The occurrence at distinct times of events normally synchronous; disturbance of coordination.

1447 Superficial vascularization of the cornea with infiltration of granulation tissue; an inflammatory exudate overlying the lining layer of synovial cells on the inside of a joint.

1448 The property of being attracted by a magnet, and of assuming a position parallel to that of a magnetic force, but not of becoming permanently magnetized.

1449 An arbitrary constant in a mathematical expression that distinguishes specific cases; a parameter has a definite fixed value in one case but will have different values in another case.

1451 Particles introduced by the device during the procedure.

1455 Effected or performed through the skin.

1457 The escape of blood around a heart valve, particularly around its leaflets.

1458 In radiology, a device that stimulates the conditions encountered when radiation or radioactive material is deposited in vivo and permits a quantitative estimation of its effects.

1463 Electrical stimulation of the patient's pocket of skin in which the pulse generator is housed.

1470 A potentiometer is a device used for the measurement of an electromotive force by comparison with a known potential difference.

1471 A potentiometer is an device used for the measurement of an electromotive force by comparison with a known potential difference.

1478 A substance separating, in solid particles, from a liquid as the result of a chemical or physical change; to form a precipitate.

1498 The closure of the pulmonary artery or one of its branches by an embolus, sometimes associated with infarction of the lung.

1505 A fever producing substance.

1507 The occurrence of a premature ventricular complex near the peak of the T wave in electrocardiography; it may lead to ventricular tachycardia or fibrillation.

1518 A tube for insertion into a duct or cavity.

1522 A backward or return flow.

1538 Membrane separation process for removing solvent from a solution; typically used as a water purification process in hemodialysis.

1556 The sediment filters used to remove particulates from the water supply, in order to protect other water treatment equipment or dialysate delivery devices, become clogged or damaged.

1578 To provide with or divert by means of an electrical shunt; to divert blood from one part to another by a surgical shunt.

1593 Condition where there are a greater number of inhalations relative to the number of exhalations.

1602 Breakage of supporting pieces of a heart valve.

1610 A temporary suspension of consciousness due to generalized cerebral ischemia; a faint or swoon.

1629 Discrepancies occurring during automatic data measurement and transmission, as by wire or radio, from remote sources, to a receiving station for recording and analysis.

1631 Use of a medical device for therapeutic purposes.

1633 Loss of the minimum amount of energy, voltage, or current needed to consistently stimulate the heart muscle.

1634 The amount of gas that is inspired and expired during one respiratory cycle.

1640 Lens with a cylindrical component; used for correcting an eye's astigmatic refractive error.

1648 A sharp-pointed instrument equipped with a cannula, used to puncture the wall of a body cavity and withdraw fluid.

1656 The transfer of fluid between the blood and dialysate through the dialysis membrane due to a pressure gradient (transmembrane pressure) existing between the blood and dialysate compartments.

1677 Ionic exchange process used in hemodialysis to treat water.

1684 A disease characterized by opportunistic infections.

1688 The premature expulsion from the uterus of the products of conception, of the embryo or of a nonviable fetus.

DEFINITIONS (continued)

1689 Abraded wound; excoriation or circumscribed removal of the superficial layers of the skin or mucous membrane.

1690 Circumscribed collection of pus appearing in an acute or chronic, localized infection and associated with tissue destruction and frequent swelling.

1692 Failure of the smooth muscle fibers of the gastrointestinal tract to relax at any one point of junction of one part with another.

1695 The process of adhering or uniting of two surfaces or parts, especially the union of the opposing surfaces of a wound.

1696 Fulminant pulmonary interstitial and alveolar edema, which usually develops a few days after the initiating trauma.

1697 The presence of bubbles of gas in the vascular system; occurrence is related to the entry of air into the venous circulation following trauma or surgery.

1701 Hypersensitivity; a local or general reaction of an organism following contact with a specific allergen to which it has been previously exposed and to which it has become sensitized.

1703 Pertaining to anaphylaxis.

1704 Systemic anaphylaxis is the most dramatic example of an immediate hypersensitivity reaction; is uncommon and unexpected in nature and occasionally results in a fatal outcome.

1705 An opening created by surgical, traumatic or pathological means between two normally distinct spaces or organs.

1706 Equilibrium between blood loss and blood production is disturbed, resulting in a reduction in the number of erythrocytes.

1707 The amount of anesthesia administered to the patient was inadequate.

1708 A sac formed by the dilation of the wall of an artery, a vein or the heart.

1710 Severe constricting pain, usually relating to the heart muscle.

1711 Absence or lack of oxygen; reduction of oxygen in body tissues below normal levels.

1714 Serving to prevent the coagulation of blood. Any substance that delays, or nullifies coagulation of the blood.

1715 Defective functioning of the aortic valve, with incomplete closure resulting in aortic regurgitation.

1716 The backward flow of blood from the aorta into the left ventricle, owing to insufficiency of the aortic semilunar valve; it may be chronic or acute.

1717 Narrowing of the orifice of the aortic valve or of the supravalvular or subvalvular regions.

1718 A numerical expression of a newborn infant's, physical condition, usually determined at 60 seconds after birth.

1719 Any procedure in which blood is withdrawn from a donor, a portion is separated and retained, and the remainder is retransfused into the donor.

1720 Cessation of breathing.

1721 Any variation from the normal sinus rhythm of the heart.

1722 A group of diseases characterized by thickening and loss of elasticity of arterial walls.

1724 A chronic, systemic disease primarily of the joints, usually polyarticular, marked by inflammatory changes in the synovial membranes and articular structures and by muscle atrophy and rarefaction of the bones.

1725 The inspiratory sucking into the airways of fluid or a foreign body.

1727 Cardiac standstill or arrest; absence of a heartbeat.

1728 An extremely common form of arteriosclerosis in which deposits of yellowish plaques containing cholesterol, lipoid material and lipophages are formed within the intima and inner media of large and medium sized arteries.

1729 An arrhythmia in which minute areas of the atrial myocardium are in various uncoordinated stages of depolarization and repolarization; instead of intermittently contracting, the atria quiver continuously in a chaotic pattern, causing a totally irregular, often rapid ventricular rate.

1730 A condition of cardiac arrhythmia in which the atrial contractions are rapid (250 to 350 per minute) but regular.

1731 A rapid cardiac rate usually between 160 and 190 beats per minute.

1732 Any disorder in which destruction of normal tissue arises from humoral or cellular immune responses of the individual to their own tissue constituents; it may be systematic or organ specific.

1733 The immune response in which antibodies or immune lymphoid cells are produced against the bodies own tissues.

1736 Cirrhosis of the liver due to obstruction or infection of the major extra-or intrahepatic bile ducts.

1739 Bleeding within the cerebrum.

1741 Bleeding within the cranium.

DEFINITIONS (continued)

1742 Loss of the sense of sight.
1745 The patient's blood becomes contaminated from contact with blood/fluids on a device.
1747 Unintended collection/stasis of blood in patient.
1750 An eating away; destruction of the surface of a tissue, material or structure.
1751 Slowness of the heart beat, as evidenced by slowing of the pulse rate to less than 60.
1754 An injury of a part without a break in the skin.
1755 A burn caused by exposure to x-ray, radium, sunlight, atomic or any other type of radiant energy.
1757 Injury to tissues caused by contact with dry heat, moist heat, chemicals, electricity, friction or radiant and electromagnetic energy. A first degree burn is associated with redness, a second degree burn with vesication and a third degree burn with necrosis through the entire skin.
1758 The process by which organic tissue becomes hardened by a deposit of calcium salts within its substance.
1761 The tightening of scar tissue that forms around the implant.
1762 Sudden cessation of the pumping function of the heart, with disappearance of arterial blood pressure, connoting either ventricular fibrillation or ventricular standstill.
1763 A bruise to the heart.
1764 A general diagnostic term designating primary noninflammatory disease of the heart muscle, often of obscure or unknown etiology.
1765 Cessation of breathing and/or cardiac function.
1766 A loss of the transparency of the lens of the eye or its capsule.
1767 A cataract that has been produced artificially or by induction, e.g. as a result of device use, medication, trauma, tears, falls, accidental injury, etc.
1768 An acute, diffuse, spreading, edematous, suppurative inflammation of the deep subcutaneous tissues and sometimes muscle, which may be associated with abscess formation.
1770 See also Stroke Syndrome.
1771 An ischemic condition of the brain, producing a persistent focal neurological deficit in the area of distribution of the cerebral arteries.
1773 Changes such as abnormal, pathological, benign, malignant, etc.
1775 Excessive edema of the ocular conjunctiva.
1777 Inflammation of the chorion and amnion.
1778 Process of clot formation.
1779 Any disorder of blood coagulation.
1783 A clinical syndrome due to heart disease, characterized by breathlessness and abnormal sodium and water retention, often resulting in edema.
1784 Inflammation of the conjunctiva.
1785 Allergic type of conjunctival inflammation associated with continuous wearing of soft contact lenses. Hard, flat papillae form a cobblestone pattern on undersurface of upper eyelid.
1786 A group of generalized diseases affecting the connective tissue.
1787 A bruise; an injury of a part without a break in the skin.
1788 Elevation of total body temperature.
1789 Scraped area of corneal surface, accompanied by a loss of superficial tissue.
1790 Inability to maintain corneal integrity; or corneal edema resulting from failure of the corneal endothelium to maintain detumescence.
1791 Hazy, swollen cornea.
1794 Complications of intraocular lens surgery; usually refers to intraocular lens contact with cornea, can be intermittent or chronic.
1796 Area of epithelial tissue loss from corneal surface; associated with inflammatory cells in the cornea and anterior chamber.
1797 Any type of crushing injury associated with device use or operation.
1798 A bluish discoloration, applied especially to such discoloration of skin and mucous membranes due to excessive concentration of reduced hemoglobin in the blood.
1799 Inflammation of the ciliary body.
1803 Shedding of accumulated bone fragments.
1806 Deterioration; change from a higher to a lower form; especially change of tissue to a lower or less functionally active form.

DEFINITIONS (continued)

1808 An organic mental syndrome characterized by a general loss of intellectual abilities involving impairment of memory, judgement, and abstract thinking as well as changes in personality.

1812 Consisting of or containing pus; associated with the formation of or caused by pus.

1813 A disorder characterized by reduction in the elements involved in blood coagulation due to their utilization in widespread blood clotting within the vessels.

1815 Difficulty in swallowing.

1816 Difficult or labored breathing.

1817 Changes in cardiac electrical activity.

1818 A small hemorrhagic spot in the skin or mucous membrane forming a nonelevated, rounded, or irregular blue or purplish spot.

1819 Development of the fertilized ovum outside of the uterine cavity.

1820 Accumulation of an excessive amount of fluid in or around cells, tissues or body cavities.

1822 Swelling of the macula.

1823 Swelling of abnormally small red blood cells.

1826 Continued electrical rhythmicity of the heart in the absence of effective mechanical function.

1827 The passage of electrical current through the body.

1829 Sudden blocking of an artery by a clot or foreign material which has been brought to its site of lodgement by the blood current.

1830 A mass of clotted blood or other formed elements, such as bubbles of air, calcium fragments, etc. brought by the blood from another vessel and forced into a smaller one, thus obstructing the circulation.

1832 A condition of the lung characterized by increase beyond normal in the size of air spaces distal to the terminal bronchioles, either from dilatation of the alveoli or from destruction of their walls.

1833 Any degenerative disease of the brain.

1834 Inflammation of the endocardium (the endothelial lining membrane of the heart and the connective tissue bed on which it lies).

1835 Inflammation involving the ocular cavities and their adjacent structures.

1839 To belch, the casting of upwind from the stomach.

1840 Redness of the skin produced by congestion of the capillaries.

1841 Extensive loss of blood due to internal or external hemorrhage.

1842 A discharge or escape, as of blood, from a vessel into the tissues.

1843 Extreme fatigue; inability to respond to stimuli.

1844 Thrusting or pushing out; expulsion by force.

1846 Weakening or paralysis of the facial nerve.

1847 Extremely weak; threatened with syncope.

1851 Stopping of the pulse. A condition due to lack of oxygen in respired air, resulting in impending or actual cessation of life.

1852 Injury occurring as a result of the delivery process.

1854 Elevation of total body temperature.

1855 Death in utero; failure of the product of conception to show evidence of respiration, heart beat, or definite movement of a voluntary muscle after expulsion from the uterus, with no possibilitiy of resuscitation.

1858 Elevation of body temperature above normal.

1860 Inflammation and fibrous degeneration of a muscle.

1861 The formation of fibrous tissue; fibroid or fibrous degeneration.

1862 An abnormal passage or communication, usually between two internal organs, or leading from an internal organ to the surface of the body.

1863 Failure of direct anchorage of an implant by the formation of bony tissue around the implant without the growth of fibrous tissue at the bone-implant interface.

1864 A sudden or brief burst of light.

1865 Gas or air in the gastrointestinal tract.

1866 "Spots before the eyes"; deposits in the vitreous of the eye, usually moving about and probably representing fine aggregates of vitreous protein occurring as a benign degenerative change.

1868 A granulomatous inflammatory reaction evoked by the presence of an exogenous material in the tissues, a characteristic feature of which is the formation of foreign body giant cells.

DEFINITIONS (continued)

1869 Feeling of grittiness or having something in the eye; frequently caused by a foreign body. Other possible causes include corneal abrasion, corneal ulcer, inturned eye lash or acute conjunctivitis.
1870 The breaking of a part; e.g. a bone, tooth, etc.
1871 A sudden compelling urge to urinate.
1873 Death of tissue, usually in considerable mass and generally associated with loss of vascular (nutritive) supply and followed by bacterial invasion and putrefaction.
1874 Inflammation of the stomach.
1875 A group of eye diseases characterized by an increase in intraocular pressure which causes pathological changes in the optic disk and typical defects in the field of vision.
1876 Any small nodular delimited aggregation of mononuclear inflammatory cells.
1884 A localized collection of blood, usually clotted, in an organ, space, or tissue, due to a break in the wall of a blood vessel.
1885 The removal of certain elements from the blood by virtue of the difference in the rates of their diffusion through a semipermeable membrane.
1886 The destruction of red blood cells and the subsequent release of hemoglobin into the plasma.
1887 The expectoration of blood or of blood-stained sputum.
1888 The escape of blood from the vessels; bleeding.
1889 Hemorrhage into the cerebrum. See also Stroke Syndrome.
1890 Intracranial hemorrhage into the epidural space.
1891 Bleeding within the cranium, which may extradural, subdural, subarachnoid, or cerebral.
1892 Extravasation of blood into the ventricular system of the brain.
1893 Intracranial hemorrhage into the subarachnoid space.
1894 Cerebral hemorrhage into the subdural space. See also Stroke Syndrome.
1895 The arrest of bleeding, either by the physiological properties of vasoconstriction and coagulation or by surgical means.
1896 A collection of blood in the pleural cavity.
1897 Inflammation of the liver.
1898 Any inflammatory skin disease caused by a herpesvirus and characterized by the formation of small vesicles in clusters.
1900 Urticaria.
1903 Excessive concentrations of bilirubin in the blood, which may lead to jaundice.
1904 The presence of an increased amount of blood in a part or organ; engorgement.
1905 Abnormally high concentration of glucose in the circulating blood.
1906 The abnormal multiplication or increase in the number of normal cells in normal arrangement in a tissue.
1907 A state of altered reactivity in which the body reacts with an exaggerated immune response to a foreign substance.
1908 Persistently high arterial blood pressure.
1909 Abnormally high body temperature; especially that induced by therapeutic purposes.
1910 Abnormally prolonged, rapid, and deep breathing.
1911 Hemorrhage within the anterior chamber of the eye; bloodshot.
1912 An abnormally small concentration of glucose in the blood.
1913 An accumulation of pus in the anterior chamber of the eye.
1914 Abnormally low blood pressure.
1915 Abnormally low body temperature.
1916 A state in which there is a reduced amount of air entering the pulmonary alveoli.
1917 Shock resulting from insufficient blood volume for the maintenance of adequate cardiac output, blood pressure and tissue perfusion.
1918 Decrease below normal levels of oxygen in inspired gases, arterial blood or tissue.
1922 Denoting any adverse condition in a patient occurring as the result of treatment by a physician or surgeon, especially infections acquired by the patient during the course of the treatment.
1923 Relating to or affecting the cardiac ventricles alone.
1924 An object or material, such as an alloplastic or radioactive material or tissue, partially or totally inserted or grafted into the body for prosthetic, therapeutic, diagnostic, or experimental purposes.
1925 Lack of power.

DEFINITIONS (continued)

1926 Dysfunction of one of the cardiac valves, with incomplete valve closure resulting in valvular regurgitation.
1927 One that is abnormally prone to dilate in the second trimester of pregnancy, resulting in premature expulsion of the fetus.
1928 Inability to control excretory functions.
1931 The diffusion or accumulation in a tissue or cells of substances not normal to it or in amounts in excess of the normal.
1933 Infection within the eye.
1936 Changes in the fluid pressure inside the eye.
1937 Increase of pressure of the intraocular fluid in the eye.
1938 The entrance of foreign matter into a blood vessel.
1940 Inflammation of the iris.
1942 Deficiency of blood in a part due to functional constriction or actual obstruction of a blood vessel.
1944 Inflammation of the cornea.
1945 Keratitis due to infection by acanthamoeba; it is usually associated with soft contact lens wear, particularly overnight wear.
1948 Failure of adequate output by the left ventricle despite an increase in distending pressure and in end-diastolic volume, with dyspnea, orthopnea, and other signs and symptoms of pulmonary congestion and edema.
1949 Enlargement or overgrowth of the myocardium of the left ventricle, due to chronic pressure overload.
1950 Any pathological or traumatic discontinuity of tissue or loss of function of a part.
1953 Bruising of the liver.
1956 A localized destruction or degeneration of the skin caused by various cutaneous diseases.
1957 Opportunistic infection of the retina by cytomegalovirus, seen in patients with immunodeficiency; symptoms include retinal necrosis and hemorrhage, leading to blindness.
1959 Deviations from the normal process; e.g. delayed, difficult, profuse, scanty, unusual bleeding, etc.
1960 A tiny cyst, frequently of such dimensions that a magnifying lens or microscope is required for observation.
1961 Small holes made through a part or a substance.
1962 Loss of the products of conception from the uterus before the fetus is viable; spontaneous abortion.
1963 Defective functioning of the mitral valve, with incomplete closure resulting in mitral regurgitation.
1964 The backward flow of blood from the left ventricle into the left atrium, owing to insufficiency of the mitral valve; it may be acute or chronic, usually due to mitral valve prolapse, rheumatic heart disease or a complication of cardiac dilatation.
1965 Narrowing of the left atrioventricular mitral orifice.
1966 A sudden, violent, involuntary contraction of a muscle or group of muscles.
1968 Stiffness or inflexibility.
1969 Gross necrosis of the myocardium, as a result of interruption of the blood supply to the area, as in coronary thrombosis.
1970 An unpleasant sensation; symptoms resulting from an inclination to vomit.
1971 Pathologic death of one or more cells, or a portion of tissue or organ, resulting from irreversible damage.
1978 New blood vessel formation in abnormal tissue or in abnormal positions.
1983 Functional disturbances or pathological changes in the peripheral nervous system.
1984 The act of closure or the state of being closed; an obstruction.
1992 A chronic inflammatory disease of the skeletal muscle, characterized by symmetrical weakness of the limb girdles, neck and pharynx, usually associated with pain and tenderness, and sometimes proceeded or followed by manifestations typical of scleroderma, arthritis, systemic lupus, erythematosus or Sjorgen's Syndrome.
1997 Loss or impairment of motor function in a part due to lesion of the neural or muscular mechanism.
1998 A slight or incomplete paralysis.
1999 A peeling off or loss of epidermis, as in sunburn, postscarlatinal peeling, or toxic epidermal necrolysis.
2000 Any pelvic infection involving the upper female genital tract beyond the cervix.
2004 Inflammation of a vein.
2009 The assumption of various distinct forms by a single organism or species; also the property of crystallizing in 2 or more forms.
2010 The presence of fluid in the pleural space.
2011 Inflammation of the lungs with consolidation.

DEFINITIONS (continued)

2012 Accumulation of air or gas in the pleural space, which may occur spontaneously or as a result of trauma or a pathological process or to be induced deliberately.
2013 Erosion of patient's skin pocket which houses a device.
2014 Abnormally large eyeball.
2015 Antibodies directed against nuclear antigens; almost invariably found in systemic lupus erythematosus and are frequently found in rheumatoid arthritis, scleroderma, Sjogren's Syndrome and mixed connective tissue disease.
2020 Abnormal, diffuse, extravascular accumulation of fluid in the pulmonary tissues and air spaces due to changes in hydrostatic forces in the capillaries or to increased capillary permeability.
2021 Localized necrosis of lung tissue caused by obstruction of the arterial blood supply, most often due to pulmonary embolism.
2022 Defective functioning of the pulmonary valve, with incomplete closure resulting in pulmonic regurgitation.
2023 The backflow of blood from the pulmonary artery into the right ventricle, owing to insufficiency of the pulmonic semilunar valve.
2024 Narrowing of the opening between the pulmonary artery and the right ventricle, usually at the level of the valve leaflets.
2026 An obstruction of the pupil.
2027 A liquid inflammation product consisting of leukocytes and the debris of dead cells and tissue elements.
2028 Inducing fever.
2034 Intermittent bilateral attacks of ischemia of the fingers or toes and sometimes of the ears or nose, marked by severe pallor, and often accompanied by paresthesia and pain.
2035 A reaction that occurs at or about the site of infection or the point of injection.
2036 A reaction pertaining to or affecting the body as a whole.
2038 Lay term applied to any condition with dilation of conjunctival or ciliary blood vessels; innumerable causes, especially irritation and infection.
2039 Chronic, irreversible renal failure.
2041 The inability of a kidney to excrete metabolites at normal plasma levels under conditions of normal loading or the inability to retain electrolytes under conditions of normal intake.
2044 Cessation of breathing.
2045 Difficulty breathing.
2046 A condition of the newborn marked by dyspnea with cyanosis, most frequently occurring in premature infants, children of diabetic mothers and infants delivered by cesarean section, and sometimes with no predisposing cause.
2051 Moving backward; degenerating; reversing the normal order of growth and development.
2052 Moving backward or against the usual direction of flow.
2053 The most important manifestation of and sequel to rheumatic fever, consisting chiefly of valvular deformities.
2055 Failure of proper functioning of the right ventricle, with venous engorgement, hepatic enlargement, and subcutaneous edema.
2056 Enlargement or overgrowth of the myocardium of the right ventricle, due chronic pressure overload.
2058 A species comprising the yellow-pigmented, coagulase-positive pathogenic forms of the genus, causing serious suppurative infections and systemic disease; they produce toxins that cause food poisoning and toxic shock syndrome.
2059 The interval from the end of ventricular depolarization to the onset of the T wave; it is usually isoelectric in normal subjects.
2060 Formation of new tissue formed in the healing of a wound.
2062 Chronic hardening and thickening of the skin, which may be a finding in several different diseases, occurring in a localized or focal form and as a systemic disease.
2063 An attack or recurrence of a disease; a single episode of epilepsy.
2064 A simple partial seizure consisting of clonus or spasm of a muscle or muscle group; it may be single or in a continuous and repetitive series or may spread to adjacent muscles.
2066 Administration of antigen to induce a primary immune response; exposure to allergen that results in the development of hypersensitivity.
2067 The presence in the blood or other tissues of pathogenic microorganisms or their toxins.
2068 Shock associated with overwhelming infection, most commonly infection with gram-negative bacteria.
2069 A tumor-like collection of serum in the tissues.

DEFINITIONS (continued)

2071 Any contagious disease acquired during sexual contact; eg. syphilis, gonorrhea, chancroid.

2072 A sudden disturbance of mental equilibrium; a condition of profound hemodynamic and metabolic disturbance characterized by failure of the circulatory system to maintain adequate perfusion of vital organs.

2073 A symptom complex of unknown etiology, marked by the triad of keratoconjunctivitis sicca, xerostomia, and the presence of a connective tissue disease, usually rheumatoid arthritis but sometimes systemic lupus erythematosus, scleroderma or polymyositis.

2075 A gradual breakdown or very shallow ulceration of the skin which involves only the epidermis and heals without scarring.

2084 Chocking or arrest of respiration due to occlusion of the air passageway; arrest of circulation in a part due to compression.

2085 Decrease in the caliber of a canal, duct, or other passage, as a result of cicatricial contraction or the deposition of abnormal tissue.

2086 A sudden and severe attack.

2088 The stopping of respiration or the asphyxia that results from it.

2089 Decentration, or malposition of intraocular lens; zonular dehiscence or lens malposition caused by zonular or parsplana fixation.

2094 Inflammation of a synovial membrane.

2095 Rapid beating of the heart, usually applies to a heart rate above 100 beats per minute.

2097 Pertaining to tears involving the tentorium of the cerebellum.

2098 Children affected by toxins may be due to silicone breast implants and their effects on unborn children and from breastfeeding.

2100 Clotting within a blood vessel which may cause infarction of tissues supplied by the vessel.

2101 An aggregation of blood factors, primarily platelets and fibrin with entrapment of cellular elements, frequently causing vascular obstruction at the point of its formation.

2103 A noise in the ears, such as ringing, buzzing, roaring, clicking.

2107 "Fringe of pointed tips"; An atypical rapid ventricular tachycardia with periodic waxing and waning of amplitude of the QRS complexes on the electrogram as well as rotation of the complexes about the isoelectric line.

2108 A severe illness caused by infection with staphylococcus aureus and characterized by high fever of sudden onset, vomiting, diarrhea, and myalgia, followed by hypotension and in severe cases, shock; a sunburn-like rash with peeling of the skin, especially of the palms and soles, occurs during the acute phase.

2109 A brief attack (from a few minutes to an hour) of cerebral dysfunction of vascular origin, with no persistent neurological deficit.

2111 Incomplete closure of the tricuspid valve, resulting in tricuspid regurgitation; it is usually secondary to systolic overload in the right ventricle.

2112 The backflow of blood from the right ventricle into the right atrium, owning to imperfect functioning/insufficiency of the tricuspid valve.

2113 Narrowing or stricture of the tricuspid orifice of the heart.

2114 Dislodgement, breakdown, or other malfunction of an artificial cardiac pacemaker, chemotherapy port, drip infusion valve, or similar implanted diagnostic or therapeutic device as a result of unconscious or habitual manipulation by the patient.

2115 (Uveitis, Glaucoma, Hyphema) For complications that occur secondary to intraocular lens implantation in the anterior chamber; caused by rubbing of the lens loop (haptics).

2116 The formation or development of an ulcer.

2117 Denotes that a patient is resting and not under the influence of any medications.

2118 Denotes that the patient is resting and not under the influence of any sedatives.

2119 Accumulation of urine within the bladder because of the inability to urinate.

2122 An inflammation of part or all of the uvea, the middle (vascular) tunic of the eye, and commonly involving the other tunics (the sclera, cornea and retina).

2126 The diminution of the caliber of vessels, especially constriction of arterioles leading to decreased blood flow to a part.

2127 A state of increased caliber of the blood vessels.

2128 Spasm of the blood vessels, resulting in decrease in their caliber.

2129 Puncture of a vein, usually to draw blood or to inject a solution.

DEFINITIONS (continued)

2130 Arrhythmia characterized by fibrillary contractions of the ventricular muscle due to rapid repetitive excitation of myocardial fibers without coordinated contraction of the ventricle.

2131 A ventricular tachyarrhythmia characterized electrocardiographically by smooth undulating waves with QRS complexes merged with T waves, a rate of approximately 250 per minute.

2132 An abnormally rapid ventricular rhythm with aberrant ventricular excitation, usually in excess of 150 beats per minute.

2134 An illusory sense that either the environment or one's own body is revolving.

2150 Establishing a pouch of what was formerly an enclosed cyst.

2152 The large vessels entering the heart, including the aorta, the pulmonary arteries and veins, and the venae cavae.

2154 Thrusting or pushing out; expulsion by force.

2156 A deficiency of immune response or a disorder characterized by deficient immune response.

2158 Unequal refraction or focalization of light rays by a lens, resulting in degradation of the image they produce.

2159 A wrong or mistaken diagnosis.

2161 An involuntary, compulsive, repetitive stereotyped movement, usually of the face or shoulders.

2164 An objective visual sensation that appears with the eyes closed and in the absence of visual light.

2165 A nonimmunologic, chemically induced type of photosensitivity.

2168 A symptomatic form of epilepsy often preceded by an aura; characterized by loss of consciousness with generalized tonic-clonic seizures.

2169 Epilepsy characterized by absence seizures.

2171 A sensation as of repetitive pin pricks, caused by cold or by striking a nerve, or as a result of various diseases of the central or peripheral nervous system.

2172 The occurrence of a single contraction or a series of contractions of a muscle.

2174 To penetrate a tissue or substance.

2178 Associated with contact lens wear, due to an inadequate spreading of the tear film over the cornea as a result of incomplete and/or infrequent blinking.

2181 Inflammatory intraocular reaction with clouding and cells in vitreous; often accompanies inflammation of ciliary body, iris, choroid, or retina.

2186 Headache in erect position, after lumbar puncture; due to lowering of intracranial pressure by leakage of cerebrospinal fluid through the needle tract.

2187 A syndrome characterized by hyperbilirubinemia and deposition of bile pigment in the skin and mucous membranes with a resulting yellow appearance of the patient.

2188 An excess in the blood of urea, creatinine, and other nitrogenous end products of protein and amino acid metabolism.

2189 Any of a group of diseases that although clinically distinct and not necessarily related etiologically, have in common widespread pathologic changes in the connective tissue; they include lupus erythematosus, dermatomyositis, scleroderma, polyarteritis nodosa, thrombotic purpura, rheumatic fever, and rheumatoid arthritis.

2191 Shivering or shaking, accompanied by a sense of cold and pallor of the skin.

2192 A violent jar or shock, or the condition which results from such an injury.

2193 Painful, spasmodic muscular contractions.

2194 A sensation of unsteadiness with a feeling of movement within the head.

2195 Impairment of speech.

2196 Higher or lower than normal values for the serum electrolytes; usually affecting NA, K, CHL, CO2, glucose, bun.

2197 A cytopathic retrovirus. It is the etiological agent of AIDS.

2198 Normal location of the mediastinum changes to the right or left, depending upon the underlying cause.

2201 The escape of blood around a heart valve, particularly around its leaflets.

2206 Inability of the heart to pump blood at an adequate rate to fill tissue metabolic requirements or the ability to do so only at an elevated filling pressure.

2207 The condition resulting from the spread of bacterial products (toxins) by the bloodstream.

2209 Asphyxia in utero due to hypoxia. See also fetal hypoxia.

2210 Hypoxia in utero, caused by conditions such as inadequate placental function (often abruptio placentae), preeclamptic toxicity, prolapse of the umbilical cord, or complications from anesthetic administration.

2211 Induced abortion.

DEFINITIONS (continued)

2212 All products of conception are expelled and identified.
2213 The uterus is not entirely emptied of its contents.
2214 Abortion brought on intentionally.
2215 Retention in uterus of an abortus that has been dead at least 4 weeks.
2216 Abortion induced to save the life or health of a pregnant woman.
2217 Inflammation of the amnion.
2218 Resembling anaphylaxis.
2220 Appearance of enlarged infected cells altering cell formation and possible loss of fetus.
2221 A violent involuntary contraction or series of contractions of the voluntary muscles; seizure.
2222 A convulsion marked by alternating contracting and relaxing of the muscles.
2223 Prolonged contraction of the muscles, as the result of an epileptic discharge.
2224 A severe, often fatal encephalopathy which has been attributed to accumulation in the brain of aluminum from dialysate prepared with inadequately purified water.
2225 An excretion or substance evacuated.
2226 Acute compression of the heart caused by increased intrapericardial pressure due to the collection of blood or fluid in the pericardium from rupture of the heart, penetrating trauma, or progressive effusion.
2227 Hazy ring around bright lights seen by some patients with refractive error or optical defects, e.g. cataracts, or corneal swelling.
2228 Diffuse edema of the central region of the cornea, usually associated with the wearing of hard contact lenses, but may also occur in keratoconus.
2231 Discrete, small lesions present in the cornea as a result of corneal inflammation and, in some cases, after soft contact lens wear especially extended-wear lenses.
2232 Very small, round vesicles containing fluid and cellular debris observed on the surface of the cornea under slit-lamp examination in some types of corneal dystrophy and in wearers of extended-wear lenses.
2233 The capability of the cornea to respond to stimulation.
2234 Ocular pain which may be very intense, accompanied by corneal epithelium damage, conjunctival injection, lacrimation, blepharospasm, photophobia and hazy vision following corneal edema caused by overwear of contact lenses, principally the PMMA type.
2236 Toxic substance from gram-negative bacteria that has a broad spectrum of biological activities, including pyrogencity.
2237 A group of lung disorders characterized by obstruction of air flow, particularly on exhalation. The most common COPD disorders include chronic bronchitis, emphysema, asthma, and bronchiectasis.
2238 Pain in a muscle or muscles.
2239 A symptom complex characterized by nervousness, chest pain, back pain, palpations, pruritus, and other usually mild symptoms occurring minutes following the initiation of dialysis with a new dialyzer.
2240 A protrusion of a loop or knuckle or an organ or tissue through an abnormal opening.
2241 A smooth, slightly elevated area on the body surface, which is redder or paler than the surrounding skin. It is the typical lesion of urticaria, the dermal evidence of allergy, and in sensitive persons may be provoked by mechanical irritation of the skin.
2242 Excessive amount of sodium in the blood. A hazard associated with the use of softeners in hemodialysis.
2243 Abnormally decreased volume of circulating fluid (plasma) in body.
2244 Infection produced by direct contact with another person.
2245 Infection transmitted by water, food or other means of conveyance.
2246 An infection caused by pus-producing organisms.
2247 Infection associated with no detectable symptoms but caused by microorganisms capable of producing easily recognizable diseases, such a poliomyelitis or mumps.
2249 Pass from one part of the body or organ to another.
2250 Free from fever producing substances.
2252 Inflammation of the peritoneum.
2253 Polymyositis occurring in association with characteristic inflammatory skin changes.
2254 A physical response to the presence of endotoxins in the bloodstream, which is characterized by fever and occasionally chills and shaking rigors.
2255 A cutaneous inflammatory reaction occurring as a result of exposure to biologically effective levels of ionizing radiation.

DEFINITIONS (continued)

2256 Radiation induced skin desquamation.

2259 Flow in the opposite direction from normal, as the casting up of undigested food or gas from the stomach, or the backward flowing of blood into the heart, or between the chambers of the heart when a valve is incompetent.

2260 Partial seizure.

2261 The seizure seen in absence epilepsy, consisting of a sudden momentary break in consciousness of thought or activity, often accompanied by automatisms or clonic movements, especially of the eyelids.

2262 Shock resulting from primary failure of the heart in its pumping function, as in myocardial infarction, severe cardiomyopathy, or mechanical obstruction or compression of the heart.

2263 Narrowing or stricture of a duct or canal.

2264 A hypoglycemic reaction to overdosage of insulin, a skipped meal, or strenuous exercise in an insulin-dependent diabetic.

2265 Shock resulting from neurogenic vasodilation, which can be produced by cerebral trauma or hemorrhage, spinal cord injury, deep general or spinal anesthesia, or toxic central nervous system depression.

2266 A state of shock following a surgical operation.

2267 Shock that occurs during or after a surgical operation.

2268 Any shock produced by trauma.

2269 Acquired as an adult.

2270 Passed from mother to fetus.

2273 An agent or factor that induces or increases the incidence process that affects the production of a malformed fetus.

2274 A local defect, or excavation of the surface of an organ or tissue, which is produced by the sloughing of inflammatory necrotic tissue.

2275 Urination at short intervals without increase in daily volume of urinary output, due to reduced bladder capacity.

2278 A vascular reaction, usually transient, involving the upper dermis, representing localized edema caused by dilatation and increased permeability of the capillaries, and marked by the development of wheals.

2279 An anemia resulting from the destruction of red blood cells.

2285 Impedance is the resistance met by alternating electrical currents passing through a conductor.

2295 Process which involves the exchange of ions of sodium for the calcium and magnesium in the water supply, thus lowering to an acceptable range the otherwise high levels of these elements typically found in feed water.

2297 Failure to indicate the presence of bubbles in the extracorporeal circuit during cardiopulmonary bypass.

2300 The air eliminator vents and eliminates air from the cardioplegia delivery system during cardiopulmonary bypass.

2304 Failure of the stopcock valve to regulate or stop the flow of a fluid through a tubule structure.

2308 Process used in water purification systems in hemodialysis.

2314 Interference from sources of energy outside a system or systems, as contrasted to electromagnetic interference generated inside systems.

2315 System used to purify water in hemodialysis.

2317 Equipment becomes contaminated from blood/fluids coming from the patient, and must be discarded.

2318 Unintended collection/stasis of blood in device.

2327 Patient becomes entangled or caught in side rails of bed.

2336 A condition with sudden onset caused by acute vascular lesions of the brain, such as infarction from hemorrhage, embolism, thrombosis or rupturing aneurysm. See also: cerebrovascular accident (CVA), cerebral hemorrhage and subdural hemorrhage.

2352 Consisting of abnormally decreased sensitivity, particularly to touch.

2353 Consisting of abnormally decreased sensitivity, particularly to touch.

2354 Consisting of abnormally decreased sensitivity, particularly to touch.

2355 Pain in a joint.

2358 Removal of scar tissue.

2359 A vague feeling of bodily discomfort and fatigue.

2362 Paralysis of the nerves located in the legs.

2363 Difficulty moving; distortion or impairment of voluntary movement, as in tic, spasm, or myoclonus.

2364 A type of metabolic acidosis produced by accumulation of ketone bodies resulting from uncontrolled diabetes mellitus.

DEFINITIONS (continued)

2367 Inflammation of the pharynx.

2372 Excision of the apex of the petrous portion of the temporal bone.

2375 Inflammation of fascia.

2389 Inflammation of the meninges, usually by either a bacterium or a virus.

2390 A chronic adhesive arachnoiditis in the spinal arachnoid, with root and spinal cord symptoms similar to those caused by pressure from a tumor.

2393 The creation of an opening in the anterior trachea for insertion of a tube to relieve upper airway obstruction and to facilitate ventilation; a surgical creation of an opening into the trachea through the neck.

2430 A decrease in the fraction of the forced vital capacity that is exhaled in a specific number of seconds.

2431 An increase in the fraction of the forced vital capacity that is exhaled in a specific number of seconds.

2435 A decrease of the greatest rate of flow that can be achieved during forced expiration, beginning with the lungs fully inflated.

2436 An increase of the greatest rate of flow that can be achieved during forced expiration, beginning with the lungs fully inflated.

2479 The measurement of the mean left arterial pressure, as measured by a catheter introduced into the distal pulmonary artery, is low.

2480 The measurement of the mean left arterial pressure, as measured by a catheter introduced into the distal pulmonary artery, is high.

2481 The measurement of the mean left arterial pressure, as measured by a catheter introduced into the distal pulmonary artery, is normal.

PART II - DEVICE MANUFACTURER CODES
(For Section H, Blocks H3 and H6 of Form 3500A)

SUBPART A - DEVICE EVALUATED BY MANUFACTURER (Block H3)

CODES USED FOR A "NO" RESPONSE (ordered alphabetically)

02 Device evaluation anticipated, but not yet begun
03 Device not made by company
04 Device problem already known, no evaluation necessary
01 Device received in a condition which made analysis impossible
81 Other (code unspecified, describe in H10)

SUBPART B - EVALUATION CODES (Block H6)

METHOD OF EVALUATION CODES (ordered alphabetically within each section)

SOURCE OF DEVICE EVALUATED

11 A device from same lot of the actual device involved in incident was evaluated
10 Actual device involved in incident was evaluated
13 Device from controlled/non-released inventory evaluated
12 Device from reserve sample evaluated

TYPE OF EVALUATION PERFORMED

36 Analysis of labeling performed
39 Chemical tests; e.g. corrosion, reaction
21 Computer hardware performance tests conducted
22 Computer software performance tests conducted
20 Device evaluated with respect to operational environment
25 Electrical tests of all specifications performed
23 Electrical tests performed
82 Environmental tests; temperature, humidity and vibration
30 Mechanical tests of all specifications performed
26 Mechanical tests performed
27 Mechanical tests, dynamic - fatigue test
28 Mechanical tests, static - tension or compression failure
84 Optical tests of all specifications performed
86 Other (code unspecified, describe in H10)
83 Pathological evaluation of returned device (i.e. vascular grafts, heart valves, etc.)
33 Performance tests of all specifications performed
31 Performance tests performed
34 Performed test to determine if incident was the result of interaction with another device(s)
37 Photographic images made during evaluation
35 User-device interface test performed
38 Visual examination

RESULTS OF EVALUATION CODES (ordered alphabetically within each category)

CATEGORY A - DEVICE

703 Alarms inadequate or absent
101 Component/subassembly failure (select specific code from Category D)
103 Computer hardware problem
104 Computer software problem
105 Computer/human interface problem
705 Controls, switches, keypads difficult to read or use
704 Critical information not displayed
110 Design (unspecified)
115 Design - maintenance difficult
112 Design - not fail safe
114 Design - operational context
111 Design - packaging deficiencies
113 Design - user interface
706 Device difficult to assemble or set up

RESULTS OF EVALUATION CODES

CATEGORY A - DEVICE (continued)

708 Device performed according to specifications
702 Display hard to read or misleading
120 Electrical problem (unspecified)
122 Electrical problem - open circuit
123 Electrical problem - operating outside specifications
121 Electrical problem - short circuit
197 Electro-magnetic interference problem
198 Electro-static interference
133 End of life - expected
134 End of life - premature
138 Exceeded expected life of device
140 Expected wear/deterioration
141 Failure to cycle
142 Foreign material contamination
196 Inadequate optical transmission
143 Inadequate quality assurance/control
102 Incompatible components
168 Instructions not available
144 Insulation degradation/deterioration
154 Labeling contains inadequate instructions for use/maintenance
157 Labeling contains incorrect instructions for use/maintenance
151 Labeling difficult to read/see
152 Labeling difficult to understand
153 Labeling does not provide necessary information
156 Labeling is incomplete
159 Labeling is not available
150 Labeling problems (unspecified)
145 Lubrication excessive
146 Lubrication insufficient
147 Lubrication, loss of
148 Lubrication, wrong SAE (specifications)
149 Lubrication, wrong type used - oil vs grease
170 Manufacturing
174 Manufacturing - materials
171 Manufacturing - packaging
172 Manufacturing - process
173 Manufacturing - quality control
175 Manufacturing - user interface
135 Material degradation/deterioration, anticipated or expected
137 Material degradation/deterioration, unanticipated or unexpected
136 Material problem - post production
180 Mechanical problem (i.e. pump, motor, wiring, cable, battery, parts, friction, etc.)
710 Negative results of device testing
709 None
707 Operating steps confusing
100 Other (code unspecified, describe in H10)
190 Out of specification
160 Package insert information inadequate/incorrect
167 Package insert missing
162 Package labeling inadequate/incorrect
163 Package mislabeled
131 Premature power source depletion
132 Premature RRT indicator (recommended replacement time)
191 Quality assurance
164 Service manual (use in conjunction with another labeling code)
192 Shelf life exceeded
195 Sterilization
193 Storage/shipment
194 Telemetry failure
176 Tolerance stack-up (hardware/software)
165 User instruction manual (use in conjunction with another labeling code)
701 User/device interface

CATEGORY B - USE OF DEVICE

201 Cleaning error
213 Device used according to labeled indications
214 Device used in appropriate environment
202 Device used with inappropriate material
215 Device used with incompatible equipment
203 Device used with incompatible medium/material
204 Disinfection error
205 Failure to follow instructions
206 Failure to remove packaging per use instructions
207 Failure to service/maintain according to manufacturer recommendations
208 Incorrect technique/procedure
209 Misapplication/misuse of device
223 Modification of device - by authorized service organization
225 Modification of device - by distributor
224 Modification of device - by other service organization
221 Modification of device - by user/user facility biomedical engineering department
220 Modification of device - unspecified
236 Negative results of device testing
235 None
200 Other (code unspecified, describe in H10)
230 Reuse of device - unspecified
232 Reuse of device beyond labeled specifications

RESULTS OF EVALUATION CODES

CATEGORY B - USE OF DEVICE (continued)

234 Reuse of device without following disinfection/sterilization instructions
231 Reuse of disposable device
233 Reuse of single use device
211 Timing error
212 Unapproved use of device

CATEGORY C - PHYSIOLOGICAL / PROCEDURAL FACTORS

311 Anticipated adverse reaction - long term
312 Anticipated adverse reaction - short term
310 Anticipated or known (physiological/ procedural related, but code unspecified)
321 Caused by another drug/device
323 Caused by magnetic field - MRI
324 Caused by metal - microwave
325 Caused by operational context
331 Environmental factors
332 High/low temperature or humidity
313 Inherent risk of procedure
314 Known long term complication of procedure
315 Known short term complication of procedure
346 Negative results of device testing
345 None
300 Other (code unspecified, describe in H10)
333 Patient diagnosis contraindicated use of device
316 Patient's condition - predisposed event
317 Patient's condition affected effectiveness of device
318 Patient's condition contraindicated use of device
322 Related to another drug/device
326 Related to operational context
334 Support system problem (e.g., facility oxygen flow system, electrical Failure of entire facility)
340 Unanticipated (physiological / procedural related, but code unspecified)
341 Unanticipated adverse reaction - long term
342 Unanticipated adverse reaction - short term
343 Unanticipated long term complication of procedure
344 Unanticipated short term complication of procedure

CATEGORY D - DEVICE COMPONENT / SUBASSEMBLY FAILURES

401 Absorber (CO2)
548 Accumulator
402 Actuator
431 Adapter
552 Air cleaner
549 Air pump assembly
403 Alarm
404 Alarm, assembly
405 Alarm, audible
407 Alarm, high inspiratory pressure
408 Alarm, LED
409 Alarm, low inspiratory pressure
410 Alarm, oxygen pressure
411 Alarm, power
412 Alarm, pressure
550 Alarm, self
413 Alarm, visual
414 Alarm, volume
590 Alternator
591 Altimeter
592 Amplifier
593 Analyzer
594 Annunciator
595 Antenna
596 Arrester
597 Attenuator
598 Backpanel
599 Backplane
417 Bacterial filter
730 Baffle
553 Bags
418 Ball
731 Ballast
419 Balloon
732 Barrier
420 Battery
733 Beam splitter
734 Bearings
735 Bell
737 Belt
738 Blower
739 Bobbin
740 Bolometer
741 Bolt
554 Bottom dead center sensor bracket
742 Brake
422 Breathing circuit
743 Brush
745 Bus
746 Bushing

CATEGORY D - DEVICE COMPONENT/SUBASSEMBLY FAILURES (continued)

736 Buzzer
423 Cable
747 Calibrator
748 Camera
749 Cannula, inner
750 Cannula, outer
424 Cap
751 Capacitor
555 Capacitor (ceramic chip)
752 Carrier
556 Cascade
425 Cassette
753 Caster
754 Cell
426 Charger
755 Chassis
756 Choke
427 Circuit board
757 Clamp
758 Clip
759 Clock
428 CO2 monitor
429 CO2 monitor subassembly (only use when part of another device)
760 Coder
761 Coil
762 Collimator
763 Comparator
557 Compressor (air pump)
558 Concentrator
559 Conductor coil
560 Connecting rod
435 Connector
764 Contact lens
436 Control switches
765 Controller
766 Converter
767 Cooling module
768 Cord
769 Core
770 Counter
771 Coupler
772 Cover
437 CPU (central processing unit) board
561 Crank arm assembly
438 CRT (cathode ray tube)
773 Crystal
562 Cuff
563 Cup seal
774 Cups
775 Current limiter
776 Current source
439 Cusp
777 Cutter
440 Cylinder
441 Cylinder valve
778 Damper
779 Data acquisition unit
780 Decoder
442 Defibrillator paddles
443 Defibrillator subassembly (only use when part of another device)
781 Dehumidifier
782 Dehydrator
783 Delay line
784 Demagnetizer
785 Demodulator
786 Densitometer
787 Detector
788 Device deployer
789 Dial
445 Diaphragm
790 Digitizer
447 Diode
448 Discrete component/device (resistor, capacitor, diode)
791 Disk
416 Display
792 Divider
793 Dome
794 Doubler
795 Driver
796 Duct
797 Dummy load
798 Duplexer
450 EKG/ECG monitor
449 EKG/ECG subassembly (only use when part of another device)
452 Electrical lead
451 Electrode
799 Emitter
800 Enclosure
801 Encoder
802 Endoscope
454 EPROM (erasable programmable read only memory)
803 Equalizer
804 Evaporator
455 Exhalation filter
805 Expander
806 Extender
807 Extractor
808 Eyelet
456 Fail-safe system
809 Fan
810 Fastener
811 Feedthru

CATEGORY D - DEVICE COMPONENT/SUBASSEMBLY FAILURES (continued)

812 Ferrule
813 FET (field effect transistor)
814 Fiber
815 Film
816 Filter
457 Flange
817 Flasher
458 Flowmeter
818 Foil
819 Foot pedal
459 Foot switch
820 Frame
460 Function indicator
564 Function lid
821 Furnace
822 Fuse
461 Gas scavenging
823 Gasket
462 Gauges/meters
824 Gear
565 Gears
825 Generator
826 Grille
827 Grommet
828 Ground strap
829 Guide
463 Guidewire
830 Handset
464 Header
831 Headphone
832 Heads
833 Headset
465 Heart valve cage
466 Heart valve leaflet
834 Heart valve sewing ring
835 Heat exchanger
836 Heat sink
467 Heater
566 Heater rod
567 Helifix coil
837 Hinge
838 Holder
468 Hollow fiber
839 Housing
469 Hub
470 Humidifier
471 Hybrid circuit
474 IC (integrated circuit)
472 IC (integrated circuit) chip
840 Igniter
841 Imager
842 Impedance converter
843 Indexer
844 Indicator
845 Inductor
473 Insulation
846 Integrator
847 Intercom
569 Interconnection board intubate
848 Interface
849 Interrupter
850 Inverter
851 IOL (intraocular lens) implant
852 Isolator
853 Jack
854 Joint
855 Joystick
856 Jumper
857 Junction
475 Keyboard
858 Keyer
859 Keypad
860 Kit
861 Knob
862 Label
863 Laminate
864 Lamp
865 Laser
476 Lead conductor
477 LED (light emitting diode)
866 Lenses
478 Limit switch
867 Limiter
868 Line conditioner
570 Line cord
479 Lithium iodide battery
869 Load
870 Lock
571 Locking sleeve
480 Logic board
572 Lower piston bearing
481 Luer valve
871 Magazine
482 Magnet
872 Magnetizer
873 Magnetometer
874 Magnetoresistor
875 Magnifier
483 Manifold
876 Matrices
484 Membrane
877 Memory
878 Meter
573 Meter needle
879 Microcircuit
880 Microphone
881 Microscope
882 Mirror

CATEGORY D - DEVICE COMPONENT/SUBASSEMBLY FAILURES (continued)

883 Mixer
884 Modem
885 Modulator
886 Monitor
485 Mother board
486 Motor
574 Motor roll pin
887 Mount
888 Multiplier
889 Nebulizer (only use when part of another device)
890 Network
1023 None
891 Nuts
487 O2 monitor subassembly (only use when part of another device)
892 O2 sensor
488 Obturator
894 Optical cable
893 Optical disk
546 Optical fiber
895 Optocoupler
896 Oscillator
897 Oscilloscope
400 Other (code unspecified, describe in H10)
898 Outlet
899 Oven
575 Overlay
489 Oximeter
490 Oximeter (only use when part of another device)
491 Oxygen analyzer
900 Pad
901 Panel
492 PC (printed circuit) board
902 Photodetector
903 Photomultiplier
904 Phototransistor
905 Pickup
493 Pilot balloon valve
906 Pin
576 Piston guides
577 Piston heads
578 Piston Pads
494 Pivot
907 Plate
908 Plotter
579 Plug
910 Pointer
911 Polarizer
495 Port
912 Post
496 Potentiometer
497 Power cord
580 Power lamp
913 Power module
498 Power supply
499 Power switch
914 Preamplifier
915 Prescaler
916 Preselector
500 Pressure sensor
581 Pressure signal
501 Pressure tubing
917 Printer
918 Probe
919 Processor
920 Programmer
503 PROM (programmable read only memory)
504 Prong
921 Protector
922 Proximity switch
923 Pulley
924 Pulser
925 Pump
926 Pyrometer
927 Rail
505 RAM (random access memory)
928 Reactor
929 Reader
930 Receiver
507 Recorder (tape, stripchart, etc.)
931 Rectifier
582 Reed (electrically open)
932 Regulator
508 Relay
933 Repeater
934 Reservoir
935 Resistor
936 Resolver
937 Resonator
938 Retainer
583 Retaining pin
939 Reticle
940 RFI (radio-frequency interference)
941 Rheostat
942 Ribbon
943 Ring
944 Rivet
945 Robot
946 Rod
509 ROM (read only memory)
947 Safety interlock
984 SAW (surface acoustic wave device)
949 Scale
948 Scaler
950 Scanner
951 Scintillometer

CATEGORY D - DEVICE COMPONENT/SUBASSEMBLY FAILURES (continued)

952 Scrambler
953 Screen
568 Screw
954 Scriber
432 Seal
584 Seal tracheal
510 Sensor
551 Servo
955 Shaft
956 Shield
957 Shift register
958 Shifter
959 Shunt
960 Shutter
961 Signal conditioner
962 Simulator
963 Slide
964 Slip ring
965 Slotter line
967 Socket
966 Socket adaptor
511 Solder joint
512 Solenoid
968 Sound absorber
969 Spacer
970 Spark gap
971 Speaker
972 Spectrometer
514 Spirometer
973 Splicer
974 Spooler
975 Spring
976 Stabilizer
977 Stand
515 Stent
516 Stepper motor
978 Stiffener
517 Stopcock
979 Strain relief
980 Strip line
518 Stylet
981 Substrate
982 Sunlamp
983 Suppressor
519 Switches
985 Synchronizer
986 Synthesizer
987 Syringe
988 Table
989 Tachometer
990 Tape
991 Tee
520 Telemetry equipment
992 Telephone
993 Teleprinter
994 Teletypewriter
995 Television unit
996 Temperature compensator
997 Terminal
585 Terminal assembly
998 Terminator
999 Thermistor
1000 Thermocouple
547 Thermocouple wire
1001 Thermometer
1002 Thermostat
1003 Thyristor
1004 Timer
586 Tip conductor coil
1005 Trackball
1006 Transceiver
522 Transducer
523 Transformer
524 Transistor
1007 Translator
1008 Transmission line
1009 Transmitter
1010 Transponder
1011 Transport
1012 TRIAC
1013 Trimmer
525 Tube
587 Tube capillary
1014 Tuner
444 User interface
527 Valve
528 Valve (one-way, hemo, stopcock, etc.)
529 Valve, control
530 Valve, directional
589 Valve, dump
531 Valve, exhalation
532 Valve, flap
533 Valve, flow
534 Valve, inhalation
535 Valve, inlet port
536 Valve, inspiratory
537 Valve, outlet port
538 Valve, PEEP (positive end expiratory pressure)
539 Valve, pressure limit
540 Valve, relief
541 Valve, safety
542 Valve, selector
543 Vaporizer
1015 Varistor
588 VDT (video display terminal)
1016 Vibrator
1017 Viewer
1018 Voltmeter

RESULTS OF EVALUATION CODES

CATEGORY D - DEVICE COMPONENT/SUBASSEMBLY FAILURES (continued)

1019 Washer
1020 Waveguide
1021 Window
430 Wire
544 Wiring harness
545 Y-piece connector
1022 Yoke

CATEGORY E - COMPUTER-, IMAGING SYSTEM-, MICROPROCESSOR-CONTROLLED DEVICE PROBLEMS

617 Algorithm analysis
618 Algorithm problem
657 Bus conflicts
633 Bus corruption
635 Calculation error (pentium)
653 Cache controller
652 Cache memory
601 Central processing unit/operating system - error/design
643 Cold
628 Communication
663 Compression errors
603 Computer - user interface
602 Computer hardware problem
605 Computer software problem
616 Computer software problem - error/design
658 Conducted interference
626 Data corruption
631 Deadlock
647 Dirt
655 DMA controller (direct memory access)
646 Dust
664 Electromagnetic interference
648 Electrostatic discharge
630 Glitch
642 Heat
645 Humidity
656 I/O (input/output) controller
627 I/O (input/output) integrity
637 Interrupt errors
621 Kernel
638 Latch-up
644 Liquid ingress
606 Magnetic interference
607 Medical diagnosis software
654 Memory access errors
629 Metastable state
608 Modem/communications failure
665 None
600 Other (code unspecified, describe in H10)
609 Poor image resolution
659 Power fluctuation
610 Power loss/surge related complication
662 Power sequencing
661 Power spike
660 Power transient
640 Power-up errors
641 Radiation effects
622 Real-time operating system
639 Reset errors
611 RF interference
612 Safety interlock/feature failure
625 Sequence processing
650 Shock
636 Stack errors
619 State machine
651 Temperature fluctuation
634 Timing violation
620 Token
632 Transmission effects
613 User installation error
614 User maintenance error
624 Vector processing
649 Vibration
623 Watchdog

CONCLUSION CODES (ordered alphabetically)

40 Another device caused failure
70 Device discarded - unable to follow-up
71 Device evaluated and alleged failure could not be duplicated
72 Device evaluated and alleged failure could not be duplicated - cause of event unknown
41 Device failed during assembly
64 Device failed during pre-test/pre-trial
42 Device failed just prior to use
43 Device failure directly caused event
44 Device failure directly contributed to event
45 Device failure indirectly caused event
46 Device failure indirectly contributed to event

CONCLUSION CODES (CONTINUED)

47	Device failure occurred and was related to event
48	Device failure occurred but not related to event
49	Device failure related to maintenance
61	Device failure related to user handling
50	Device failure/lack of effectiveness related to patient condition
51	Device maintenance contributed to event
65	Device operated according to specifications
63	Device repaired and returned
52	Device was out of calibration
53	Device was out of specification but this does not relate to event
54	Device was out of specification in a manner that relates to event
55	Intermittent failure directly caused event
56	Intermittent failure directly contributed to event
57	Labeling related
67	No conclusion can be drawn
78	No device failure
74	No failure detected and product within specification
75	No failure detected but product out of specification
76	Operational context caused event
77	Operational context contributed to event
68	Other (code unspecified, describe in H10)
58	Software/firmware caused event
59	Software/firmware contributed to event
88	This is a report of an accidental radiation occurrence (ARO), submitted pursuant to 21 CFR 1002.20
66	Unusual event
79	User error caused event
80	User error contributed to event
62	User interface contributed to event
60	User-interface caused event